STRATEGIC ASSESSMENT ISSUE PAPER

DSI 7: MATERIALS/MEDICAL OVERSIGHT

INTRODUCTION

In August 1995, the Nuclear Regulatory Commission (NRC) staff initiated a Strategic Assessment and Rebaselining Project. This project was intended to take a new look at the NRC by conducting a reassessment of NRC activities in order to redefine the basic nature of the work of the agency and the means by which that work is accomplished, and to apply to these redefined activities a rigorous screening process to produce (or rebaseline) a new set of assumptions, goals, and strategies for the NRC. The results of this project are intended to provide an agency-wide Strategic Plan which can be developed and implemented to allow the NRC to meet the current and future challenges.

A key aspect of this project was the identification and classification of issues that affect the basic nature of NRC activities and the means by which this work is accomplished. These issues fall into three categories. The first category includes broad issues defined as Direction-Setting Issues (DSIs). DSIs are issues that affect NRC management philosophy and principles. The second category includes subsumed issues. Subsumed issues are those that should be considered along with the DSIs. The third category includes related issues. These are issues that should be considered after the Commission makes a decision on the option(s) for a DSI. Also, as part of the project, other issues of an operational nature were identified. These are not strategic issues and are appropriately resolved by the staff, and are not discussed in the issue papers.

Following the reassessment of NRC activities, issue papers were prepared to provide a discussion of DSIs and subsumed issues, and to obtain a review of these broad, high-level issues. These papers are intended to provide a brief discussion of the options as well as summaries of the consequences of the options related to the DSIs. Final decisions related to the DSIs will influence the related issues which are listed, but not discussed, in each issue paper. As part of the Strategic Assessment and Rebaselining Project, the issue papers are being provided to interested parties and to the public. Following distribution of the issue papers, a series of meetings are planned to provide a forum to discuss and receive comment on the issue papers. After receiving public comment on the issue papers, the Commission will make final decisions concerning the DSIs and options. These decisions will then be used to develop a Strategic Plan for the NRC. In summary, the Strategic Assessment and Rebaselining Project will analyze where the NRC is today, including internal and external factors, and outline a path to provide direction to move forward in a changing environment.

I. SUMMARY

A. Direction-Setting Issue

The Nuclear Regulatory Commission (NRC) Byproduct Materials Program currently regulates approximately 6,400 specific and 35,000 general licenses for the possession and use of nuclear materials in medical, academic, and industrial applications. The Materials Program includes licensing and inspection activities, primarily administered by the NRC regional offices, and exempt distribution licenses and sealed source and device (SS&D) reviews, which are handled by NRC Headquarters. The various regulated products and uses range from large quantities of radioactive materials in complex devices or in the manufacture of radiopharmaceuticals to small quantities in radioactive tracer studies or in simple devices. The NRC is evaluating the level of control and regulation needed to oversee its diverse Nuclear Materials Program. Many of the applications pose similar risks and could be regulated by other Federal and State agencies. Specifically, the NRC has been considering whether to continue to regulate or to revise its oversight of the medical uses of nuclear byproduct materials. To obtain input on the medical regulation issue, the NRC contracted with the National Academy of Sciences (NAS), Institute of Medicine (IOM), to perform an external review and to assess the adequacy and appropriateness of the current regulatory framework. The IOM final report, "Radiation in Medicine: A Need for Regulatory Reform," provides recommendations to give regulatory authority over medical uses to the States, with a Federal agency other than the NRC providing leadership and guidance[1]. A decision on the Medical Use Program may effect a rethinking of the NRC's fundamental philosophy on the extent to which it should regulate other nuclear materials. This issue paper provides options associated with the Direction-Setting Issue (DSI) of what should be the future role and scope of the NRC's Nuclear Materials Program, and in particular, NRC's regulation of the medical use of nuclear material. The options include expanding, retaining and revising, retaining in part, or eliminating the Nuclear Byproduct Materials Program with particular emphasis on medical use.

B. Options

Option 1: Increase Regulatory Responsibility With Addition of X-Ray, Accelerators, and Naturally Occurring and Accelerator-Produced Radioactive Materials

This option would transfer the regulatory responsibility for non-Atomic Energy Act of 1954, as amended (AEA), sources of ionizing radiation, such as x-ray, linear accelerators, and naturally occurring and accelerator-produced

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[1] See Attachment, "Regulation of Radiation in Medicine - IOM Issues"

radioactive materials (NARM), from other Federal agencies and the States to the NRC. An Agreement States Program would continue. Legislation would be required to implement this option.

Option 2: Continue Ongoing Program (With Improvements)

This option would maintain the current regulatory responsibility of the NRC and the States, while making continual improvements to increase efficiency and revising regulations to be more risk-informed and performance-based rather than prescriptive. Some of these improvements are currently ongoing (business process reengineering [BPR]) or are on temporary hold (revision of Part 35 of Title 10 of the Code of Federal Regulations [10 CFR Part 35]). Legislation would not be required.

Option 3: Decrease Oversight of Low-Risk Activities With Continued Emphasis of High-Risk Activities

This option would decrease regulatory responsibility for all materials that pose a low risk to the workers and the public. Examples of these materials include diagnostic nuclear medicine, gas chromatographs, some portable gauges, and so on. The NRC would retain oversight of SS&D reviews, manufacturers and distributors, and high-risk applications, such as medical therapy, radiography, and large irradiators. Specific regulations and guidance in the high-risk area would be revised to make them more risk-informed and performance-based.

Option 4: Discontinue Regulation of All Medical Activities Except NRC Oversight of Devices and Manufacturers (National Academy of Sciences Recommendation)

In this option, the regulatory authority over all medical uses of byproduct material would be given to the States, with a Federal agency (not NRC) in a guidance leadership role. The NRC would retain authority for SS&D reviews, manufacturers and distributors, and all nonmedical applications. Findings under Section 81 of the AEA for exemption or legislation would be required to discontinue NRC responsibilities over medical uses. Legislation would be required to give authority to the States and to name a lead Federal agency.

Option 5: Discontinue Materials Program

In this option, the regulatory authority for byproduct material applications would be given to another Federal agency or the States, with the assumption that an acceptable level of safety would be maintained. The NRC would have no remaining authority for any byproduct materials oversight. Legislation would be required.

II. DESCRIPTION OF ISSUES

A. Background/Bases

The key considerations in reexamining the role and scope of NRC's Byproduct Materials Program, and specifically its regulation of the medical use of byproduct material, are NRC's responsibilities as defined by the AEA to protect public health and safety, the common defense, and the environment. Although the Byproduct Materials Program must be performed in response to the AEA, the AEA also provides NRC with broad authority regarding the standards and processes that it applies in implementing this responsibility. This issue paper addresses the extent or scope of a Byproduct Materials Oversight Program necessary to ensure adequate protection in the use of byproduct materials.

Section 81 of the AEA directs the NRC to regulate the manufacture, production, transfer, receipt in interstate commerce, acquisition, ownership, possession, import, and export of byproduct material. Among other things, Section 81 authorizes the NRC "to issue general or specific licenses to applicants seeking to use byproduct material." Byproduct material is defined in Section 11e(1) of the AEA as nuclear materials created or made radioactive by exposure to the radiation during the fissioning process in a reactor. As provided under the AEA, the NRC also regulates Federal licensees in all States. The NRC has only limited responsibility, however, for regulating uses of nuclear material by the Department of Energy or the Department of Defense.

The nuclear materials licensees can be categorized into several major groups covering various products and uses regulated by the NRC and the Agreement States, under either a specific license or a general license.[2]

1. Specific Licensed Nuclear Materials

These groups include (1) broad-scope materials licenses; (2) manufacturers and distributors; (3) hospitals, clinics, nuclear pharmacies, and private physicians; (4) limited research and development operations; (5) measuring systems; (6) irradiators; (7) industrial radiography; (8) well logging; and (9) other material licenses. All of these licensees are regulated under applicable provisions in 10 CFR Parts 19, 20, and 30 for byproduct materials. In addition, individual sections of Title 10 provide specific requirements for some activities, such as medical, radiography, and irradiators.

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[2] In addition, the Commission has exempted certain nuclear material uses, activities, and products from regulation. The most widely exempted products are residential smoke detectors that contain small quantities of americium-241.

Presented below are descriptions of the major groups of nuclear materials licensees regulated by NRC and the Agreement States that require a specific license.

a. Broad-Scope Materials Licenses

The broad-scope licensees include universities, medical schools, large medical centers, large manufacturers, and research and development facilities that cannot operate under a more limited specific license without seriously disrupting their programs. These licensees use nuclear materials for a wide variety of activities, including research and development, laboratory testing, and medical diagnosis and therapy. Broad-scope licenses authorize the use of any byproduct material by anyone in accordance with review and approval procedures and criteria established by the radiation safety committee. Under the broad-scope license, the NRC places significant reliance on the organization's radiation safety committee and radiation safety officer to ensure that NRC's regulations are met. At present, the NRC regulates about 300 broad-scope licensees.

b. Manufacturers and Distributors

Manufacturers and distributors of nuclear materials include those that fabricate SS&Ds (e.g., brachytherapy sources, portable gauges, radiography cameras), as well as those that make radiopharmaceuticals. The manufacturers usually use unsealed nuclear materials that must be controlled to a greater extent than sealed materials. Currently, NRC licenses 129 manufacturers and distributors under 10 CFR Part 32. Twenty of these manufacturers also have received broad-scope licenses from the NRC.

c. Hospitals, Medical Clinics, Nuclear Pharmacies, and Private Physicians

The Medical Use Program represents approximately one-third of NRC's nuclear materials licensees and includes uses of byproduct material in medical diagnosis, therapy, and research. Currently, there are approximately 2,000 NRC licenses authorizing the medical use of byproduct material under 10 CFR Part 35.

d. Limited Research and Development Operations

Research and development licenses are issued for possession and use of specifically designated radionuclides in academic institutions, industrial facilities, and medical institutions for nonmedical use. The NRC regulates approximately 500 limited research and development licensees under applicable sections of 10 CFR Parts 20 and 30.

e. Measuring Systems

Measuring system licenses are issued for the possession and use of measuring devices and are regulated under applicable sections of 10 CFR Parts 20, 30, and 70. Measuring systems include fixed gauges for measuring or controlling parameters, such as material density, flow, thickness, or weight; portable gauges, such as moisture-density gauges used at fixed locations; x-ray fluorescence analyzers; gas chromatographs; and others. The NRC regulates approximately 2,200 measuring system licensees.

f. Irradiators

Irradiator licensees use radiation for purposes such as sterilizing blood products, disposable medical supplies, and food and polymerizing compounds in wood finishes. Irradiators are also used for some research applications. Approximately 40 irradiator licensees are authorized, pursuant to 10 CFR Part 36, to possess radioactive material in excess of 10,000 curies each for use in irradiation activities. Several commercial NRC-licensed irradiator licensees use more than 6 million curies to process materials in their facilities. The NRC regulates 204 irradiator licensees.

g. Industrial Radiography

In industrial radiography, radiographers use sealed radiation sources to make x-ray-like pictures of metal objects such as pipes and valves. Radiography is a form of nondestructive testing that uses radiation from sealed sources (principally iridium-192 and cobalt-60) to examine the internal structure of objects. The portable radiography devices may contain radioactive sources with as much as 200 curies of iridium-192 or 100 curies of cobalt-60. The NRC has issued about 160 industrial radiography licenses pursuant to 10 CFR Part 34.

h. Well Logging

In well logging, sealed nuclear sources, unsealed radioactive trace material, and radioactive markers are used for subsurface surveying to obtain geological information. The testing procedures are primarily used in oil, gas, and mineral exploration to identify subsurface geologic formations. NRC licenses about 60 firms for well logging under the provisions of 10 CFR Part 39.

i. Other Material Licenses

The other types of materials uses that require a specific license include such diverse activities as nuclear laundries, which clean protective clothing contaminated with radioactive material; leak test and other service companies that provide services to other licensees to leak test sealed sources or

devices containing sealed sources, to analyze leak test samples, to calibrate radiation survey or monitoring equipment, or to repair devices containing sealed sources; waste disposal services; and others. The NRC has about 900 licensees performing these remaining diverse activities.

2. General Licensed Devices

Although specific licensees must submit a license application to the NRC and receive a written specific license, this is not the case for most general licensees. An NRC general license becomes effective on the basis of the general license provisions in NRC's regulations. In most cases, a general license is effective without the filing of an application with the Commission or the issuance of a licensing document to the license holder. An example would be the acceptance of a nuclear materials product at the point of sale, which would make the buyer a general licensee.

General license provisions authorize a variety of activities, such as holding title to licensed material, as well as use of licensed material contained in a device. The generally licensed devices must meet regulatory standards for design and manufacture so that they may be used by persons with minimal instruction in their proper use. (As previously discussed, manufacturers and distributors of devices intended for use under a general license must be specifically licensed for this purpose.)

Examples of these devices include static eliminators, nuclear gauges, and self-luminous signs. An NRC database indicates that there are approximately 35,000 general licensees that use about 600,000 regulated devices.

3. Exempt Distribution Licenses

In addition to specific and general license products and uses, the Commission has exempted certain nuclear material products, quantities, or concentrations from the requirements for a license and from the regulations. These exemptions have been made with prior findings that such exemptions will not constitute an unreasonable risk to the common defense and security and to the health and safety of the public. Exemptions have been authorized for products such as gemstones, watches with tritium paint, and smoke detectors, once there has been an initial transfer or distribution of the product.

4. Sealed Source and Device Reviews

The NRC further exercises its statutory responsibilities by the certification or registration of SS&Ds. SS&D manufacturers submit specific information on manufacturing techniques, prototype test results, and other data related to engineering and radiation safety to the NRC or the appropriate Agreement State. These data are evaluated and an SS&D certificate is issued after a

determination is made that the product is safe for the proposed uses. The NRC maintains a registry of SS&Ds approved by the NRC and the Agreement States. Applicants for specific licenses can reference these approved products in their applications.

B. External Factors

Notwithstanding the aforementioned oversight process, the operational history and knowledge base inherent in the current nuclear materials industry allows opportunities for streamlining NRC's Regulatory Program. The nuclear materials industry, with an operational history exceeding 40 years, has a firm foundation in the knowledge and understanding of the properties of nuclear materials and the applicable handling and radiation safety procedures, as well as the metallurgical and engineering requirements for fabricating SS&Ds. However, even with such an operational history, some factors, such as technological advances and aging equipment, may affect streamlining considerations.

1. Technological Advances

The nuclear materials industry has been and will continue to be affected by technological advances in other fields. For example, advanced computer technology has been combined with the use of sealed sources for new products and devices. This has been the case especially in radiation medicine with the advent of the gamma knife (used for brain radiosurgery) and remote afterloading brachytherapy devices. Technological enhancements are not limited to radiation medicine. As the SS&Ds are affected by more sophisticated nonnuclear technology, the regulations, review process, and qualifications of NRC technical staff required to review these applications may change. In the case of the gamma knife, for example, there are no specific medical use requirements in 10 CFR Part 35, although the regulations do address procedures for conventional cobalt-60 teletherapy devices.

2. Aging Equipment

Additionally, with a mature industry, some licensed nuclear material devices are becoming old and/or obsolete. One result may be increased mechanical and metallurgical problems. Aging devices may warrant special consideration when and if the NRC undertakes to streamline its Regulatory Program, especially in the areas of routine inspections and guidance to licensees.

3. External Interest

Unlike the organized opposition to nuclear reactors or nuclear waste disposal, the public (in most cases) has been supportive (at times, by remaining silent) on the use of nuclear materials in medicine, industry, and commerce. There

have been times, however, when the public has expressed concern about new uses of nuclear radiation (e.g., opposition to irradiation of fresh foods). For the most part, the external interests in the Materials Program have involved a few concerned citizens, licensees and their associations and professional societies, and the news media. The print media have published in-depth articles on issues such as radiation medicine misadministrations that have resulted in deaths; radioactively contaminated sites whose licenses have been terminated; and reconcentrated radioactive sewage sludges found at sewer treatment facilities. Additionally, Congress has shown and continues to show interest in the Nuclear Materials Programs of both NRC and the Agreement States.

An example of this external interest is found in the medical use of byproduct materials. During the past several years, the medical community, regulated by NRC and Agreement States, has been very vocal on specific requirements of Part 35. In general, this medical community, including physicians, physicists, pharmacists, hospitals, professional associations, and others, regards the detailed prescriptive requirements of Part 35 as unnecessarily burdensome. A specific target has been the regulation on "Quality Management Program and Misadministrations" (the QM rule), which became effective on January 27, 1992. The medical community has asserted that the requirements are an intrusion into medical practice, are cost-ineffective, and have no utility. The QM rule was strongly opposed by several professional societies, which made their views known to the Office of Management and Budget (OMB). In June 1992, OMB disapproved the record collection requirements of the QM rule on the basis that the NRC had not demonstrated that the rule would yield significant benefits. The NRC Commissioners overrode the OMB determination, citing the necessity of the information collection requirements for public health and safety. In addition, the American College of Nuclear Physicians and the Society of Nuclear Medicine took the NRC to court to overturn the QM rule. The court ruled in favor of the NRC. Shortly after, in November 1992, a patient in Indiana, Pennsylvania, died as a result of a therapy misadministration. A month later, the Cleveland Plain Dealer ran a week-long series entitled "Lethal Doses: Radiation That Kills." These events resulted in congressional hearings on NRC's Medical Radiation Program and its Agreement States Program that raised questions about the adequacy of control of the medical use of byproduct material by the NRC and the Agreement States. As a result of the two opposing, strongly held views of the regulated medical community, and Congress and the media, the Commission directed the staff to reevaluate the Medical Use Program with the assistance and advice of the NAS. To that end, the staff contracted with the Institute of Medicine of the NAS to perform the external review mentioned earlier in this issue paper. The report of that review, "Radiation in Medicine: A Need for Regulatory Reform," is discussed in the Attachment to this paper, "Regulation of Radiation in Medicine - IOM Issues"

4. Full Cost Recovery

Another significant external factor is the Omnibus Budget Reconciliation Act of 1990, which requires that the NRC recover almost 100 percent of its budget authority. The number of NRC licensees has declined since about 1990 due primarily to the requirement for full fee recovery. This declining trend will continue, with the number of licensees decreasing by about one third if States that are currently negotiating agreements (Massachusetts, Pennsylvania, Ohio, and Oklahoma) become Agreement States and additional States continue to pursue this status, The reduced number of NRC licensees will further compound the full-fee-recovery cost issue, even though the BPR efforts will likely reduce licensing fees for some categories of NRC licensees. Also, State interest in becoming an Agreement State may be reduced by NRC changes in funding for Agreement State training and technical assistance.

C. Internal Factor

In addition to the described external factors, an ongoing internal initiative could affect any decision on the role and scope of the Nuclear Materials Program.

Business Process Reengineering

In 1994, the staff began a major reevaluation of the regulatory process in NRC's oversight of licensed materials. This reevaluation is being carried out as part of a BPR effort. Phase I was completed in the spring of 1995. This phase was directed toward proposing a fundamentally new approach to materials licensing designed to (1) perform at least an order of magnitude faster than the current system; (2) be supported by clear, consistent, and timely regulatory guidance; and (3) ensure that no adverse effect on public health and safety results from its implementation. The new process will use modern information technology to streamline operations. The new approach focuses on including performance requirements in NRC's regulations, discontinuing the current practice of incorporating licensee practices and procedures in license conditions, and considering changes to the duration of materials licenses. As part of these efforts, a rulemaking has been promulgated to extend qualified materials licenses for an additional 5 years.

It is envisioned that the BPR will have a significant impact on the entire Nuclear Materials Program during the next several years. The number of licensing actions should significantly decrease, as should the amount of required review time. Inspections for certain materials licensees will be streamlined or eliminated. Overall, as a result of the reengineering efforts, the NRC's Materials Program should be significantly more efficient and responsive to both the public and licensees. During the past several years, the NRC's Materials Program has remained at about the same level in the use of

staff and resources. However, in fiscal year 1997 the program will begin to decrease in both staff and technical assistance contractual support. This decrease is due, partially, to the increased efficiencies in licensing and inspection anticipated from BPR, and partially from additional Agreement States.

III. DISCUSSIONS

A. Discussion of Direction-Setting Issue

The key considerations in reexamining the role and scope of NRC's Byproduct Materials Program, and specifically its regulation of the medical use of byproduct material, are NRC's responsibilities as defined by the AEA to protect public health and safety, the common defense, and the environment. Although the Byproduct Materials Program must be performed in response to the AEA, the AEA also provides NRC with broad authority regarding the standards and processes that it applies in implementing this responsibility.

Also to be considered is the interpretation that the Commission has adopted and implemented that medical patients are included in the "public."

The options on the role and scope of the Nuclear Materials Program are the result of management and staff review and subsequent initiatives such as the Medical Management Plan, BPR, and planned revisions to 10 CFR Parts 34 and 35. Other factors influencing the development of options included resource limitations, growth in the number of Agreement States, a desire for increased efficiency and effectiveness, and the recommendations of the IOM.

Although the primary focus of the Byproduct Materials Program is on protecting public health and safety, it must also ensure that the extent of control is tempered by the risk to the public. The focus should be on the safety-significant issues and on providing timely and consistent guidance and licensing that will allow licensees to meet the regulations and standards in the most efficient and economic way. In turn, these considerations need to be viewed in terms of a broader, changing environment. For example, it is anticipated that the number of Agreement States will increase over the next 5 years, significantly reducing the number of NRC licensees. The NRC will need to consider what steps to take to account for the anticipated reduction in resources. Although the BPR process is a step in the right direction, additional steps need to be initiated. The NRC may also have to consider changes in how it regulates areas of low public risk. This issue paper addresses the extent or scope of a Byproduct Materials Oversight Program necessary to ensure adequate protection in the use of byproduct materials.

B. Discussion of Subsumed Issue

As a part of selecting an option on the future role and scope of the NRC's Byproduct Materials Program, the following strategic issues should be considered and resolved as a result of this issue paper.

Issue: What should be the role of NRC in regulating the medical use of nuclear material?

Under the AEA, NRC has responsibility for two categories of radiation medicine use. Regulation of these two broad categories represents approximately one-third of NRC's Nuclear Materials Program. One category of radiation medicine is nuclear medicine, which employs radioactive drugs (radiopharmaceuticals). These drugs usually contain only very small quantities of radioactive material, which is used primarily for the diagnosis and followup of disease. Nuclear medicine occasionally includes the use of larger quantities of unsealed radioactive material for therapy, especially for diseases of the thyroid gland. The other category of radiation medicine is radiation therapy (radiation oncology). In radiation therapy, larger quantities of radioactive material, usually in the form of sealed sources, are used primarily in cancer treatment. Sealed quantities of radioactive material are used both external to and within a patient. Sealed radiation sources regulated under the AEA are used in about 25 percent of radiotherapy treatments. Radiation produced by electronic devices not regulated under the AEA, such as x-ray equipment and linear accelerators, is used in the other 75 percent of treatments. Therapeutic radiation devices, such as a gamma knife, may contain more than 6,000 curies, while diagnostic nuclear medicine procedures may be limited to microcurie or millicurie quantities.

By authority of the AEA and Commission policy, the NRC regulates the medical use of nuclear materials as necessary to provide for the radiation safety of workers and the general public. NRC also regulates the radiation safety of patients when justified by the risk to patients, but minimizes the agency's intrusion into medical judgments affecting patients and into other areas traditionally considered to be the practice of medicine. The NRC recognizes that physicians have primary responsibility for the protection of their patients. NRC regulations assume that authorized physician users, with appropriate training and experience, will make decisions in the best interest of their patients.

Over the years, the Commission has made a concerted effort to improve and strengthen the Medical Use Program. Following a 1976 report of hundreds of patient overexposures at Riverside Methodist Hospital in Columbus, Ohio, NRC took action to upgrade its regulation of radiation sources in medical use. Also, in February 1979, NRC issued a policy statement to guide its Regulatory Program in the medical area. A fundamental tenet in the policy statement is

the commitment to protect patient safety without intrusion into the practice of medicine. However, there has been frequent tension with the regulated medical community on a number of medical use regulatory initiatives that have been opposed by members of the regulated community as an intrusion into the practice of medicine. This tension and opposition to NRC's regulation of the medical uses of byproduct material have been a continuing problem.

Additional problems arise from the jurisdictional responsibilities for the different sources of radiation. Jurisdiction over various aspects of the regulation and use of ionizing radiation in medicine is exercised by both the Federal Government, primarily through the Department of Health and Human Services, the Food and Drug Administration (FDA) and the NRC, and the States. Within this regulatory framework, the NRC has jurisdiction over the medical use of byproduct and special nuclear material and regulates radiation safety associated with the actual use of these products. The FDA regulates the manufacture and distribution of radiopharmaceuticals, biologics, and medical devices for safety and efficacy. For the most part, FDA does not regulate at the user level. The States have broad regulatory authority over the general public health and safety of their residents. This includes authority over the use of all sources of ionizing radiation, except AEA material, which is regulated by the NRC. The States control most of radiation medicine, but the degree to which they exercise control varies from State to State.

In 1992, the staff began to develop a Medical Management Plan to guide the conduct of the Medical Use Regulatory Program. Although delayed as a result of staff actions in response to a radiation therapy misadministration and the associated patient fatality, media interest, and congressional hearings, the plan was subsequently completed and initiated. In parallel, the staff was directed by the Commission to initiate an external review of the Medical Use Regulatory Program.

As a result, NRC contracted with the NAS in 1994 for the IOM to conduct that external review, addressing not only the role of the NRC but also the roles of the FDA and the States in this area. The IOM has completed its review and recommended that regulatory authority over medical uses of byproduct material be given to the States. The IOM also recommended that only licensed users have access to byproduct material and identifies the Department of Health and Human Services (DHHS) as the agency that should exercise a leadership role in the radiation safety community. Further, the report suggests that DHHS assist in developing recommended State laws and regulations, act as an information clearinghouse, and distribute resources for training and research.

The NRC has reviewed the IOM recommendations at length and has held several public meetings on them. As of August, 1996, the NRC had received 41 comments on the subject. Although some commentors supported the recommendations, the CRCPD expressed concern about the elimination of the entire medical use

program and the absence of Federal authority in the medical use area. DHHS stated that it could not support the recommendation that it provide the leadership role suggested by IOM. A more extensive summary of the recommendations and comments appears in the Attachment to this paper, "Regulation of Radiation in Medicine - IOM Issues"

IV. OPTIONS

In this section, the five options described earlier are detailed, including, if applicable, required regulatory or legislative changes, impacts, resource implications, and the reaction of stakeholders.

Option 1: Increase Regulatory Responsibility With Addition of X-ray, Accelerators, and Naturally Occurring and Accelerator-Produced Radioactive Materials

Option

Under this option, the NRC would continue with its ongoing program and improvements and seek legislation for regulatory oversight of other sources of ionizing radiation, including x-ray, accelerators, and discrete NARM. Discrete sources of NARM include radium sources used in medicine and industry and the wastes resulting from cyclotrons and linear accelerators. They do not include wastes from the mining and processing of radium or other radionuclides. An Agreement States Program would continue. This option would significantly increase NRC's jurisdiction in the control of ionizing radiation; it would result in responsibility being taken away from other Federal agencies and the States. Variations of this option could include consideration of limiting oversight to specific applications, such as industrial and commercial uses, or to only those applications that pose a high risk (Option 3).

Regulatory Changes

Legislation would be needed to remove the responsibility for the regulation of these sources of radiation from other Federal agencies and the States and to transfer it to NRC. Coupled with this action would be new and revised policy statements, such as the 1979 Medical Policy Statement, memoranda of understanding with other Federal agencies, and agreements with the Agreement States. Rulemaking to expand and modify existing regulations and generation or revision of the companion guidance documents for the NRC staff and licensees would be necessary.

Impacts

This option would ensure increased uniformity and consistency in the regulation of all sources and uses of ionizing radiation. It would avoid substantive differences in regulations and oversight between AEA and non-AEA sources of radiation. Also, it could eliminate regulatory advantage of one radiation modality over another for a given application (e.g., x-ray radiography versus gamma radiography). This option would require an expansion of NRC's technological base to include specialists in x-ray and accelerator equipment, and the medical and commercial uses of this equipment. It would result in a significant increase in the number of NRC licensees (which would multiply 5 to 10 times), especially in the medical area. This increase would require additional personnel and physical resources, including the possibility of additional regional offices. Such wide-sweeping legislation may be difficult to support in the absence of a compelling safety problem.

The resources required to develop the necessary legislation would include resources from the other Federal agencies currently providing some radiation protection or source and device oversight (e.g., FDA, the Environmental Protection Agency [EPA]), as well as NRC. A comprehensive program that would implement such legislation, that is to regulate all discrete NARM, including promulgation of regulations, guidance development, and inspection at frequencies comparable to those of similar NRC licensees, could require several hundred full-time equivalent (FTE) positions.

The Advisory Committee on Medical Uses of Isotopes (ACMUI) would need to be expanded to include other areas of expertise such as diagnostic and interventional radiology.

Reaction of Stakeholders

As described in more detail in Option 4, the Agreement States that now have authority for non-AEA sources support the approach for a single Federal agency to be responsible for all radiation use.

Option 2: Continue Ongoing Program (With Improvements)

Option

Under this option, the current regulatory responsibility of NRC and the States would be maintained. However, there would be continual improvements to increase efficiency and revision of regulations to make them more risk-informed and performance-based rather than prescriptive. Some of these improvements are ongoing or are on temporary hold (e.g., BPR and Part 35 revisions).

The ongoing BPR of the licensing process will result in the use of modern information technology to streamline operations. The envisioned new licensing process is composed of three major concepts: (1) a Regulatory Product Design Center in which technical members of the materials licensing and inspection community can interact face to face or by way of the computer, to design and prepare the regulatory products necessary to support, maintain, and enhance the new licensing process; (2) improved processing of licenses through reviewer-performed and computer-assisted licensing, using a graded approach commensurate with the safety hazards the application poses; and (3) a new way of working in agency-wide teams. The agency-wide team concept, based on BPR philosophy, will include such attributes as collaborative team-based decisions and parallel concurrences.

In addition, NRC is identifying regulations that are obsolete, unnecessarily burdensome, too prescriptive, or that overlap or duplicate the regulations of other agencies. As part of this effort, NRC is reviewing Part 35 to evaluate whether it can be revised to reflect a more risk-informed, performance-based regulation. To this end, the staff has requested input from the ACMUI and the Agreement States on what revisions should be made to Part 35 if NRC were to retain its current statutory authority and also if NRC were to ramp down in the regulation of patient safety. Examples of staff-identified and staff-suggested requirements needing revision or possible rescission include the As Low As it Reasonably Achievable (ALARA) Program, the Quality Management Program, the misadministration definitions and reporting, dose calibrator checks, surveys, calibration of devices (using industry standards where possible), and training and experience requirements. Other sections of the regulations pertaining to materials are also being reviewed for appropriate revisions.

Regulatory Changes

No legislative changes are needed to implement this option. However, rulemaking would have to be initiated to revise the byproduct materials regulations, such as Part 35. In addition, internal guidance documents (e.g., inspection procedures, standard review plans, etc.) as well as several regulatory guides, including Regulatory Guide 10.8, would have to be revised to reflect the proposed changes.

Impacts

This option would result in the development of more risk-informed, performance-based regulations and increased agency efficiencies obtained by implementation of BPR initiatives.

Amending the regulations and modifying guidance documents and associated regulatory guides has already been budgeted as part of the Medical Management Plan. No additional resources would be necessary for the medical use area. Also, an overall reduction in needed materials resources is anticipated over the next 5 years. This reduction is predominantly due to the increased efficiencies anticipated with the implementation of planned BPR initiatives, as well as anticipation that there will be an increase in the number of Agreement States within the next 5 years. This possibility could result in a reduction of approximately 20 FTEs by the year 2000.

Reaction of Stakeholders

Based on IOM interviews and comments on the IOM report, many medical licensees would continue to support NRC's divesting itself of responsibilities in the medical area.

Option 3: Decrease Oversight of Low-Risk Activities With Continued Emphasis of High Risk-Activities

Option

This option places priority on the tenet that the regulation of byproduct materials should be consistent with the risk involved. Although the NRC has effectively regulated areas of high risk (e.g., manufacturers, large irradiators, etc.), it may be overregulating areas that involve low-risk activities or sources. Low-risk activities could include the use of devices such as gas chromatographs and certain gauges, and diagnostic nuclear medicine. The oversight of these low-risk activities may be an unnecessary expenditure of resources because of the limited additional protection it provides.

Under this option, the NRC would modify its existing regulatory responsibility of low-risk activities and maintain its current responsibility (with some program modifications) for high-risk activities. This could be accomplished through policy decisions on decreasing or discontinuing oversight in certain areas, rulemaking, or an agreed-upon definition of low risk established and coordinated with other Federal agencies, the States, and the conduct of a public comment process. This option would encompass the overall Materials Program and would affect medical as well as nonmedical programs. The low-risk applications could be placed in a category of licenses (such as general licenses) that warrants minimal regulatory oversight with no formalized inspection frequency and minimal licensing requirements. However, some audit activity might have to be established to periodically assess the general licensee's byproduct material possession and performance.

Once low risk has been defined, this option would necessitate reevaluation of those licensees currently licensed by the general license provisions, as well as those activities previously determined to be exempt from regulation. A reassessment of these licensing categories may result in moving activities and uses from one category to another.

In this option, the NRC would probably maintain its current level of regulatory oversight for the manufacturers of radiopharmaceuticals and sealed sources because these activities would most likely be considered higher risk activities.. The NRC would also maintain its current level of regulatory oversight for other high-risk applications, such as therapeutic uses of byproduct material, large irradiators, and industrial radiography. For the high-risk applications, the existing specific regulations would be revised to be more risk-informed and performance-based, or consideration may be given to limiting oversight to Part 20 compliance only.

Regulatory Changes

The transfer of some of the current specific licenses to general licenses or to some other category that warrants minimal regulatory oversight would not require legislative changes. The transfer of low-risk activities to general licenses would require modifications to current general license regulations in Part 31, as well as modifications to current licensing regulatory guides, internal standard review plans, and inspection procedures.

Impacts

This option would result in increased efficiency and effectiveness within the agency by focusing NRC's limited resources on higher risk activities and those licensees that warrant enhanced oversight because of poor performance. This option might result in the elimination of approximately 50 percent of the NRC's current specific licensee base. For the remaining high-risk licensees, the NRC would revise the applicable regulations and guidance documents using a risk-informed, performance-based approach.

It is anticipated that a few FTEs over about a year would be required to complete an analysis and recategorize licensees. If NRC completely discontinues its oversight of the low-risk activities, associated legislative efforts may also require several FTEs over several years.

With NRC either completely discontinuing its regulatory oversight of lower risk activities or reducing its oversight, the current specific licensee base could be decreased by about half. Allowing for some resources to track and audit general licensees, a reduction of approximately 50 FTEs from current licensing, inspection, and other materials activities might be realized. This reduction includes those FTEs eliminated by the BPR.

Option 4: Discontinue Regulation of all Medical Activities Except NRC Oversight of Devices and Manufacturers (National Academy of Sciences Institute of Medicine Recommendation)

Option

Under this option, the NRC would request that Congress (1) discontinue NRC's regulatory authority over all medical uses of byproduct material (including biomedical research), (2) give this regulatory authority to the States, and (3) name another Federal agency (not NRC) to a guidance leadership role. The IOM report has recommended that this Federal agency be the DHHS. The leadership role would be nonregulatory and would assist in developing recommended State laws and regulations, act as an information clearinghouse, and distribute resources for training and research. In this option, the NRC would retain responsibility for oversight of the manufacture and distribution of byproduct material (including SS&Ds) used in medicine. Further, NRC would condition these licenses to require that products could only be distributed to users who were licensed by a State. Also, the Conference of Radiation Control Program Directors (CRCPD) would continue to develop its model regulations for adoption by the States. The CRCPD would be expected to continually reevaluate its regulations to maintain congruence with any scientific advances in knowledge on radiation bioeffects, and benefits and risks of the medical uses of ionizing radiation. The NRC's ongoing program for nonmedical licensees would remain as in Option 2.

Regulatory Changes

Legislation would be needed to remove responsibility for the regulation of the medical uses of byproduct material from the AEA. In lieu of legislation, if NRC made the requisite findings under Section 81 of the AEA, the NRC could by "exemption" eliminate this aspect of the Materials Program. Rulemaking to rescind or modify regulations in Parts 30, 33, and 35, among others, would follow. This route would require public notice and comment rulemaking. Coupled with these actions would be a revision or rescission (in whole or in part) of the 1979 Medical Policy Statement, the enforcement policy, agreements with the 29 Agreement States, and the memorandum of understanding with the FDA, as well as NRC regulatory guides, manuals, and directives.

Impacts

This option would result in the elimination of approximately one-third of the NRC's current specific licensee base. The States would be responsible for all radiation medicine applications, which would result in the potential for increased uniformity of the regulation of all radiation medicine within a given State. However, the level of oversight may vary considerably from State to State because currently some States provide oversight (licensing and

inspection) through State radiologic health personnel, and others by a simple registration process. Additionally, inconsistencies could develop between regulation of basic radiation safety in medical and nonmedical applications. Finally, DHHS does not support the IOM's recommendation that DHHS be given a leadership role.

Some of the non-Agreement States may lack the resources, including qualified personnel, to set up their own safety programs and decide not to regulate in this area and both the Agreement States and the non-Agreement States may view the action as an unfunded mandate. Also, revision of the agreements with each of the 29 Agreement States would be necessary. Additionally, the event database would no longer include misadministrations or events involving overexposures to workers or members of the public (non-patients) as a result of the medical use of byproduct material. Federal facilities would be responsible for self-regulation of the medical uses of byproduct material. Proposed legislation would need to address State regulation of Federal authorities or facilities.

For those facilities conducting both biomedical and nonmedical research, there would continue to be a dual system of regulation.

Resources associated with efforts for legislation and rulemaking would entail a few FTEs for a period of about 5 years.

The Medical Use Program includes approximately 50 FTEs, which would be eliminated. The majority of these FTEs, approximately 70 percent, come from the regional materials licensing, inspection, and event evaluation activities. Also, the number of medical consultants under contract to NRC could be reduced from approximately 12 (current) to less than half that number. These consultants are used on an as-needed basis in response to medical misadministrations resulting in an overexposure, as well as nonmedical events that might require the services of a physician or a scientist consultant to assess radioactive dose estimates and possible consequences. Currently, the majority of provided services is in response to medical misadministrations.

Reaction of Stakeholders

As of the end of August 1996, the staff had received 50 written comments on the IOM report. The two major categories of responses are either in support of, or opposition to, the overall recommendations of the IOM committee. However, within each of these major categories, there are subsets with respect to the specific direction or focus of the comments. None of the comments received specifically indicated that there should be no Federal involvement.

The Secretary of the Department of Health and Human Services (DHHS), the Federal agency that would be most directly affected by the IOM recommendations, indicated that the report does not make a compelling public health agreement for DHHS to assure the recommended new role. Furthermore, DHHS raised a concern that Congress would not provide resources commensurate with the added responsibilities.

The majority of comments received (32 out of 47) did not endorse the full range of recommendations put forth by the IOM committee. Four of the 15 respondents that supported the recommendations indicated that the recommendations should encompass all uses of byproduct materials. The Department of Veterans Affairs, in its support of the IOM report, indicated that legislative initiatives should ensure that Federal facilities are not subject to State and local regulations.

The comments that did not support all the IOM recommendations varied dramatically in the focus of their viewpoints and opinions. The degree of regulatory reform perceived to be necessary ranged from simply recognizing the merits of the issues raised by the IOM committee to a need for a complete restructuring of the regulatory program. The non-Agreement States that responded were particularly concerned about the substantial financial impact of the recommendations and the issue of this being, in effect, an unfunded Federal mandate. For example, as indicated in the response from Hawaii, public health and safety could be jeopardized in those States with insufficient resources or capability to adequately implement the regulation of byproduct materials. The Department of Defense response, which summarized the responses from the three Service Medical Departments (Army, Navy, and Air Force), supported the need to re-evaluate the current regulatory structure, but emphasized the need for a uniform regulatory authority. There were several responses that recommended the need for Federal oversight for all uses of radiation.

The Organization of Agreement States response provided a summary of the consensus of the participants of the NRC and Agreement State technical workshop conducted March 5-6, 1996, which included that all radiation use (medical and non-medical uses) should be consolidated under one Federal agency. The CRCPD prepared a position paper, which supported the leadership role of a single federal agency for all forms of ionizing radiation, at their May 6 meeting. The comments of these organizations are summarized in Appendix 3 to the Attachment to this Issue Paper.

Option 5: Discontinue Materials Program

Option

Under this option, the NRC would request that Congress discontinue NRC's regulatory authority over all byproduct material uses, give this regulatory authority to the States, and name a Federal agency (not NRC) to a guidance role for all sources of radiation, as discussed in Option 4. This option presumes that an acceptable level of safety would be maintained by the States. The NRC would have no remaining authority for any byproduct materials oversight. This option is an extension of the previous option to all materials uses.

Also, there would be no change in the proper disposal of byproduct materials at low-level waste disposal sites.

Regulatory Changes

This might be viewed as subject to the procedures of the Unfunded Mandate legislation. Legislation would be needed to remove responsibility for the regulation of all uses of byproduct material from the AEA. Rulemaking would be needed to rescind the regulations in 10 CFR Parts 30 through 39, and certain policy statements and memoranda of understanding would have to be rescinded or drastically revised. Also, all agreements with the 29 Agreement States would have to be rescinded.

Impacts

In addition to the impacts described in Option 4, this option would result in elimination of NRC's oversight of all specific and general byproduct materials licenses, thereby dramatically decreasing the resources of the Office of Nuclear Material Safety and Safeguards (NMSS) and the Office of State Programs. The States would be responsible for all medical, academic, and commercial applications of byproduct materials.

The lead Federal agency could possibly serve as a safety backup if a State requested assistance. The lead Federal agency role could be filled by an existing Federal agency such as the EPA, DHHS, or the Occupational Safety and Health Administration, with legislation modifying its authorities and responsibilities. Alternatively, a new agency or office within an existing agency could be created, thereby consolidating activities currently vested among several agencies. Greater uniformity might be achieved by consolidating a guidance role in one federal agency. However, because each State would be responsible for implementing its regulatory program as it deems appropriate, there could potentially be quite diverse programs among the 50 States.

Resources associated with efforts for legislation and rulemaking would entail several FTEs over a period of 5 to 7 years.

The number of budgeted FTEs for the Byproduct Materials Program is approximately 140 FTEs in Headquarters and the regions. These FTEs include all managers and technical, administrative, and support staff. Nearly all of these FTEs could be eliminated or redirected, in part, to other activities, recognizing that a few FTEs would be needed to handle residual activities. In addition, staff from other NRC offices who support the NMSS Byproduct Materials Program could be reduced by the current number of FTEs that handle byproduct materials issues or provide support to this NMSS Program.

Reaction of Stakeholders

Reaction from the regulated community could depend on whether consensus develops among the States to follow the guidance established by the federal agency. Manufacturers of some sources and devices could be particularly concerned about the possibility of having to comply with a multiplicity of State requirements.

The Agreement States might support this option to the extent they find it consistent with their consensus view described in Option 4.

Federal agencies would self-regulate. Some indicated in their comments on the IOM report that they did not have the resources necessary to develop and implement an oversight program, as indicated in the Department of Defense's comments on that report.

V. RELATED ISSUES

After the Commission has made decisions concerning the Direction-Setting and Subsumed Issues discussed above, additional issue(s) such as those related to implementation details will be addressed as the Strategic Plan is implemented. The Related Issues are listed in this section to provide a more complete understanding of the higher level Direction-Setting and Subsumed Issues.

A. Is escalated enforcement effective in preventing future violations by materials licensees? Would it be more effective to augment the inspection process than to impose civil penalties?

This is a Commission issue because it involves the Commission's reconsideration of its policy on its Enforcement Program for materials licensees and may lead to rulemaking. It is related to the DSI because NRC's enforcement policy for materials must reflect the philosophy established by the DSI. It is a related issue rather than a subsumed issue because it will

reflect the extent to which the materials licensee community follows NRC's enforcement activities and will be addressed in more detail than is appropriate for the DSI.

B. What should be the NRC's policy relative to the need for and the frequency of renewals for materials licensees?

This is a Commission issue because a change to the current frequency of renewals will involve policy and perhaps rulemaking. This issue is related to the DSI because the DSI will establish how important materials license renewals will be in the future. It is a related issue rather than a subsumed issue because different classes of materials licensees may require different renewal policies. Such differentiation will lead to more detail than is appropriate for the DSI. The staff is actively engaged in addressing this issue.

C. What should be NRC's policy relative to frequency of renewals for fuel fabrication facility licenses?

This is a Commission issue because a change in the current frequency of renewing fuel fabrication facility licenses will involve policy and perhaps rulemaking. The issue is related to the DSI because the philosophy for renewing fuel fabrication facility licenses should be consistent with the philosophy for renewing materials licenses to be developed here. It is a related issue rather than a subsumed issue because it will reflect such aspects of fuel fabrication facility regulation as criticality concerns, which are beyond the scope of this DSI.

D. Does NRC have an acceptable program, given that history and operating experience have required revocation of very few licenses? Is there a set of licensees that NRC should be regulating differently?

Rather than revoke licenses or reject applications, NRC generally helps bring weak licensees and applicants up to acceptable standards. Such activities are often very staff-intensive and include multiple deficiency letters, pre-licensing meetings, and site visits; confirmatory action letters; increased inspection frequencies; enforcement conferences; and imposition and monitoring of "Get Well Programs." Although such activities generally bring weak licensees up to acceptable standards, this may not be the most cost-effective use of NRC's limited materials resources.

This issue, originally a subsumed issue, goes beyond the question of whether NRC should regulate a certain materials area and concentrates on the "how" or the methodology of regulation. As such, this issue will be directed by the decisions made on the Byproduct Materials Program and will require an in-depth

evaluation that is beyond the scope of the current issue paper. For these reasons, and depending on decisions by the Commission, this subsumed issue will be addressed as a related issue.

E. Should a single Federal agency regulate radiation safety?

This issue is directly linked to the Agreement States' comments on the IOM recommendations in which the Agreement States technical staffs said that "All radiation use (medical and nonmedical uses) should be consolidated under one Federal agency to include NARM, AEA material, and machine-produced radiation. Consensus was not reached as to which Federal agency should have the authority, or whether it should be an existing agency."[3]

It appears most appropriate to consider the issue of single agency jurisdiction from several perspectives. As stated above, a single agency could be responsible for radiation regardless of source, to include AEA material, NARM, and machine-produced radiation. Alternatively, a single agency could hold all authorities, to include such authorities as standard-setting (now vested in EPA), approval of medical devices and radiopharmaceuticals (now in DHHS),and applications (now in NRC).

This is a Commission issue because it involves policy concerns that are fundamental to NRC's mission, that in fact go beyond NRC's regulation of materials to include its regulation of nuclear reactors as well. It is clearly a related, rather than a subsumed, issue, because it is well beyond the scope of this DSI.

V. COMMISSION'S PRELIMINARY VIEWS

Staff actions regarding the various options should be held in abeyance pending the Commission's final decision on this issue paper.

The Commission preliminarily favors a combination of Option 2 (Continue the Ongoing Program with Improvements) and Option 3 (Decrease Oversight of Low-Risk Activities with Continued Emphasis of High-Risk Activities). In implementing Option 3, the NRC would utilize the risk-informed performance based approach, as discussed in DSI 12, to determine which activities in the materials area, and specifically in the medical area, are low-risk activities. The general approach described in Option 3 of this DSI appears to be a reasonable starting point for identifying the types of activities that can be affected by this process.

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[3] Report of Joint NRC/Agreement State technical workshop, March 5-6, 1966

In implementing these options with regard to the NRC's medical program, the NRC would consult with its Advisory Committee on the Medical Uses of Radioisotopes (ACMUI) for guidance on low-risk medical activities, revisions to 10 CFR 35, and possible implementation methods. The NRC would also evaluate the feasibility of using professional medical organizations and societies as a potential source for developing professional standards and guidance that would be adhered to by NRC medical licensees and could be adopted by the NRC as regulatory requirements.

In the public comments on this issue, the NRC particularly solicits the views of other affected organizations such as the Organization of Agreement States and the CRCPD on applying a risk-informed performance based approach to NRC's oversight of medical activities. The NRC also solicits the public's views on the feasibility and desirability of NRC's striving to have the remaining non-Agreement States acquire Agreement State authority for medical-use only. In addition, the Commission solicits the public's views on whether a single agency should regulate radiation safety. Finally, the NRC specifically seeks comments on the Attachment to this issue paper titled "Regulation of Radiation in Medicine - IOM Issues."

ACRONYMS

ACMUI	Advisory Committee on Medical Uses of Isotopes
AEA	Atomic Energy Act
ALARA	As Low as is Reasonably Achievable
BPR	Business Process Redesign
CFR	Code of Federal Regulations
CRCPD	Conference of Radiation Control Program Directors
DHHS	Department of Health and Human Services
DSI	Direction-Setting Issue
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
FTE	Full-Time Equivalent
IOM	Institute of Medicine
NARM	Naturally Occurring and Accelerator-Produced Radioactive Materials
NAS	National Academy of Sciences
NMSS	Office of Nuclear Material Safety and Safeguards
NRC	Nuclear Regulatory Commission
OMB	Office of Management and Budget
QM RULE	Quality Management Program and Misadministrations
SS&D	Sealed Source and Device

REGULATION OF RADIATION IN MEDICINE - IOM ISSUES[1]

I INTRODUCTION

Under the Atomic Energy Act (AEA), the Nuclear Regulatory Commission (NRC) regulates the medical use of reactor - generated radioactive materials to provide for the radiation safety of workers and the general public. It also regulates the radiation safety of patients when justified by the risk. NRC's responsibilities include the regulation of radiopharmaceuticals and sealed sources, but not machine-produced x-rays nor naturally occurring or accelerator produced radioisotopes.

Over the years, NRC has had a concerted effort to improve and strengthen its Medical Use Program. In these efforts, it has repeatedly addressed two difficult issues; how can it best protect patient safety without intruding into the practice of medicine; and how can it best deal with the numerous jurisdictional responsibilities for different sources of radiation? To obtain external advice on these and other issues, in 1994 the NRC contracted with the Institute of Medicine (IOM) of the National Academy of Sciences (NAS) to review NRC's Medical Use Program and to address the roles of the regulatory agencies in this area. In December, 1995, the IOM provided NRC with a prepublication copy of its report, "Radiation in Medicine - A Need for Regulatory Reform." The final report was issued in March 1996.

The report documents the committee's consideration of seven alternative regulatory systems, ranging from no regulation (laissez-faire) to Federal control of all aspects of medical care. Between these extremes, the committee considered a variety of Federal and State regulatory systems. The committee concluded that the Federal government should relinquish regulation of radiation in medicine to the States, with the Department of Health and Human Services (DHHS) providing support, coordination, and guidance to them. To bring about this change, the committee made eight recommendations; two to Congress, three to the NRC, and three to the Conference of Radiation Control Program Directors and the States.

This document provides an overview of the committee's report, including issues identified by the NRC staff about each of the recommendations, and a summary of the public comments received to date.

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[1] Some of the text in this paper closely parallels text in the Institute of Medicine report which is the subject of this paper.

The second section of this report, "Background," briefly discusses the use of radiation in medicine, the regulatory authorities of the Federal and State agencies, NRC's particular responsibilities, regulations, and activities, and a summary of the history of the NRC program which led the agency to seek a review of its Medical Use Program.

The third section of this report summarizes the IOM committee's view of the present situation, and describes the seven alternative regulatory systems considered by the committee. It describes each alternative and presents the committee's views of the positive and negative aspects of that alternative. It concludes with the committee's basis for selecting its preferred alternative, State Regulation with Federal Guidance.

The fourth section of this report addresses the committee's recommendations associated with the preferred alternative. It contains a brief description of each recommendation, a summary of the committee's rationale for the recommendation, the NRC staff's principal issues, and some pertinent public comments.

The fifth section documents NRC actions on the report to date and provides a general summary of the 47 comments received so far. Lists of specific commentors and brief summaries of their comments appear in appendices.

II BACKGROUND

This section contains a brief description of the ways ionizing radiation is used in medicine, followed by a discussion of the Federal and State regulatory authorities over that radiation. It then summarizes NRC's medical use program including its applicable regulations, its licensee community, and its activities. It then sketches the history of NRC's efforts to improve the program, including the events and issues that led NRC to seek a review by the NAS. Finally, the section documents NRC's goals for the study and the recommendations NRC requested from NAS.

Ionizing radiation is used for both diagnosis and treatment. Diagnostic uses are classified under two basic headings; radiology and nuclear medicine. In radiology, (such as the use of x-rays) the radiation administered is external to the patient; in nuclear medicine, it is internal. Nuclear medicine employs radioactive drugs (radiopharmaceuticals). When used for diagnosis or followup, these drugs usually contain only very small quantities of radioactive material.

Ionizing radiation used for treatment is also typically classified into categories depending on whether the source of radiation is external or internal to the patient. These areas are called teletherapy (external

sources), brachytherapy (internal) and therapeutic nuclear medicine (internal). Brachytherapy and teletherapy use sealed sources; therapeutic nuclear medicine uses radiopharmaceuticals. In radiation therapy, larger quantities of radioactive material, usually in the form of sealed sources, are used primarily in cancer treatment. Sealed radiation sources regulated under the AEA are used in about 25 percent of radiotherapy treatments. Radiation produced by devices not regulated under the AEA, such as linear accelerators, is used in the other 75 percent of therapy.

Regulatory authority over ionizing radiation in medicine is widely dispersed among several government agencies at the Federal, State, and local levels. At the Federal level, by authority of the Atomic Energy Act (AEA) and Commission policy, the NRC regulates the medical use of byproduct material[2] to provide for the radiation safety of workers and the general public. NRC also regulates the radiation safety of patients when justified by the risk to patients. NRC's regulatory authority is limited to byproduct material (such as cobalt^{60} or iodine^{131}), so it does not regulate naturally occurring or accelerator produced materials (NARM), or accelerator produced radiation. For example, NRC does not regulate the use of radium or x-ray equipment in medicine.

The Food and Drug Administration (FDA) in the Department of Health and Human Services (DHHS) oversees the approval of radiation-producing devices (including x-ray equipment) and radiopharmaceuticals (including NARM). In addition to these approvals, FDA's regulatory program includes review of problem reports, enforcement actions including product removal and recall, and civil prosecution of manufacturers. The Department of Transportation (DOT) regulates the transportation of radionuclides. The Environmental Protection Agency (EPA) sets generally applicable environmental standards to protect the public from radiation, and the Occupational Health and Safety Administration (OSHA) is responsible for worker safety.

States have broad regulatory authority over the general public health and safety of their residents, including authority over all sources of ionizing radiation except the authority preempted by the Federal Government as discussed above[3]. The AEA does permit States to obtain authority to regulate byproduct material by becoming one of NRC's Agreement States. In that case,

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[2] Byproduct material is defined as nuclear material created or made radioactive by exposure to radiation during the fissioning process in a reactor.

[3] Although Federal pre-emption applies to source and special nuclear material as well as byproduct material, regulation of those materials is beyond the scope of this document

the NRC formally relinquishes its regulatory authority to a State based on the NRC's determination that the State's program is adequate and compatible with NRC's. (As provided under the AEA, the NRC retains regulatory authority over Federal licensees in all States.) Presently there are 29 Agreement States.

The degree to which States exercise control over all medical uses of radiation varies from State to State. The Agreement States normally apply the standards which they have developed for NRC materials to other sources of radiation within their State, although there is no requirement that they do so. Likewise, there is no requirement for non-Agreement States to regulate the sources of radiation for which they are responsible. This situation has led to inconsistencies in the regulation of other sources of radiation in those States.

NRC's (and its Agreement States') regulation of radiation in medicine is based principally on two parts of the Code of Federal Regulations(CFR); 10 CFR Part 20, Standards for Protection Against Radiation, and 10 CFR Part 35, Medical Use of Byproduct Material. These regulations limit the amount of radiation that a worker or member of the public may receive, establish the controls that a licensee must exercise over radioactive materials, establish training and experience requirements for users of the materials, set quality management and reporting requirements, and provide a number of technical and administrative requirements for the possession and use of the materials.

NRC's medical program constitutes about one-third of its Nuclear Materials Program. Currently there are about 2,000 NRC licensees authorized for the medical use of byproduct material under 10 CFR Part 35. In addition, the 29 Agreement States have issued about 4,500 licenses authorizing the medical use of nuclear material. These medical-use licensees include hospitals, clinics, and physicians in private practice.

NRC's regulatory program consists of developing regulations and guidance issuing new licenses, and ensuring compliance. NRC promulgates new regulations and modifies existing ones through staff-initiatives or in response to petitions. NRC provides guidance to its staff and licensees by issuing regulatory guides for licensing and procedures for inspection. NRC's medical licensing activities include issuing about 85 new licenses a year, and approving about 1,400 amendments. NRC ensures compliance with its regulations by communicating safety issues to licensees, inspecting them to observe their performance, and exercising its enforcement authority over licensees who are in violation.

Over the years, and especially since the mid 1980s, the Commission has made a concerted effort to improve and strengthen the medical use program. In 1967 the Atomic Energy Commission codified its medical regulations into 10 CFR Part

35. Following a 1976 report of hundreds of patient overexposures at Riverside Methodist Hospital in Columbus, Ohio, NRC took action to upgrade its regulation of radiation sources in medical use. In February 1979, NRC issued a policy statement to guide its regulatory program in the medical area. A key issue in the policy statement is NRC's commitment to protect patient safety without intrusion into the practice of medicine. NRC regulates the radiation safety of patients when justified by the risk to patients, but minimizes the agency's intrusion into medical judgments affecting patients and into other areas traditionally considered to be the practice of medicine. The NRC recognizes that physicians have primary responsibility for the protection of their patients. NRC regulations assume that authorized physician users, with appropriate training and experience, will make decisions in the best interest of their patients. Since then, the tension inherent in NRC's commitment has arisen in a number of key medical-use regulatory initiatives that have been opposed by members of the regulated community as an intrusion into the practice of medicine. The doctor/patient relationship and NRC's regulation of medical use of nuclear material has been a continuing problem, up to the present.

A second set of problems arises from the jurisdictional responsibilities for the different sources of radiation. As discussed above, jurisdiction over various aspects of the use of ionizing radiation in medicine is exercised by a number of agencies in the Federal Government and by the States. Because of the diversity of, and occasionally overlapping, responsibilities, dual regulation or gaps in regulation may occur.

In 1992, the staff began to develop a medical management plan to guide the conduct of the medical use regulatory program. The plan was delayed as a result of staff actions in response to a radiation therapy misadministration and the associated patient fatality, media interest, and congressional hearings on administrations in both the Senate and the House. The staff subsequently completed the medical management plan, and, in parallel, was directed by the Commission to initiate an external review of the NRC's and the Agreement States' medical use regulatory program.

As a result, in January 1994, NRC contracted with the IOM to conduct that external review, including a review of NRC's regulations, policies, practices, and procedures. NRC set three goals for the study; 1) examination of the overall risk associated with the use of ionizing radiation in medicine; 2) examination of the broad policy issues that underlie the regulation of the medical uses of radioisotopes; and 3) a critical assessment of the current framework for the regulation of the medical use of byproduct material. The NRC sought specific recommendations on two major issues. First, it requested recommendations on a uniform national approach to the regulation of ionizing radiation in all medical applications, including consideration of how the regulatory authority and responsibility for medical devices sold in interstate

commerce for application to human beings should be allocated among Federal Government agencies and between the Federal and State governments. Second, the NRC requested recommendations on appropriate criteria, to measure the effectiveness of regulatory programs needed to protect public health and safety.

III IOM REPORT - ALTERNATIVES

This section presents IOM alternatives and recommendations. It begins with the IOM broad view of the regulation of radiation in medicine to provide insight into the basis for IOM decisions on the regulatory alternatives it considered and the recommendations it made.

1) IOM committee's View of the Current Situation

The IOM committee noted that NRC regulates only 10% of all ionizing radiation found in medicine, and that public health and safety would be better served by uniform regulation of all such use. It therefore concluded that NRC's current system of regulation and enforcement should be revised and that regulation of all radiation uses in medicine should be conducted by the States.

The committee examined the existing regulatory system and identified several problems that it concluded needed to be addressed. In particular, it judged the NRC's present set of regulations and its approach to regulation to be burdensome, costly, and unduly prescriptive. In addition, it found that actions taken by the NRC against user institutions, in its public announcements and its unrealistic paperwork demands, tended to be disproportionate to the violations.

The committee determined that the benefits resulting from the NRC's efforts to reduce adverse events may not be commensurate with the constraints imposed. It stated that the NRC's regulatory policy, although seemingly effective, might have gone beyond the point where "an additional dollar spent on regulation achieves an equivalent dollar benefit to patients or the public."

The committee judged that, given the strength and leadership of the Conference of Radiation Control Program Directors (CRCPD) and the *Suggested State Regulations for the Control of Radiation (SSRCR)* which the CRCPD promulgates, that State programs would remain intact and expand to cover byproduct use if Federal regulation were to be relaxed. The committee believed that all sources of ionizing radiation would be treated more uniformly, in that they would *all* be subject to State regulation.

The committee's recommendation would eliminate NRC's medical use program, but retain the basic structure of federal regulation and responsibility. In particular, the committee would have Federal agencies retain responsibility for the generation, transport, non-medical use, and disposal of radionuclides and for the approval of radiopharmaceuticals and of equipment that generates ionizing radiation. A Federal agency would assume a guidance role for the States.

2) Alternative Regulatory Systems

The committee considered NRC's request for recommendations on a uniform national approach to regulation broadly. It examined a wide spectrum of alternative structures through which all ionizing radiation in medicine might be regulated. The committee report discusses seven alternatives, which are

A Continue the Existing Situation
B Laissez-Faire (No Regulation)
C State Regulation Only
D State Regulation with Federal Guidance
E State Regulation with Reserve Federal Authority
F Centralized Federal Regulation
G Health Finance Agency

After considering the alternatives, the committee found Alternative D, State Regulation with Federal Guidance, to be its preferred choice. Brief descriptions of the seven alternatives, and the basis for the committee's choice follow.

A Continue the Existing Situation

The committee considered two ways to continue the existing situation, which it describes as A1, Status Quo, and A2, Status Quo Modified. Alternative A1, Status Quo, would be for the NRC to continue to operate exactly as it does today. Alternative A2, Status Quo Modified, would have the NRC eliminate, or announce that it will not enforce, its requirements for quality management programs (10 CFR Part 35.32) and for notifications and records of misadministrations (10 CFR Part 35.33). The committee's considered this modification because NRC has received considerable criticism from the medical community for promulgating these requirements.

The committee found no positive aspects to the Status Quo. It found a positive aspect of the Modified Status Quo in that this Alternative would not require legislative change and thus would be the easiest way to change the existing system to address the medical community's concern. Further, in the committee's view, the NRC could make useful changes to its work culture. The committee found the negative aspects of the Status Quo to be that this

alternative did not address two of the committee's concerns; first, that ionizing radiation in medicine is not treated consistently - sources used regularly in the practice of medicine are treated unevenly. The committee raised the issue of whether NRC regulation is necessary, given that NARM and machine-produced regulation has been left to the States and the FDA. Second, this alternative does not address the committee's concern that safety can be maintained at lower cost.

B Laissez-Faire (No Regulation)

In this Alternative, all forms of regulation, Federal and State, would be eliminated and responsibilities for radiation safety would be left to medical practice, medical societies, and the marketplace.

The committee found that a positive aspect of Laissez-Faire would be the cost savings resulting from an absence of regulation. The committee found negative aspects of this Alternative to be that not everybody is conscientious about radiation protection, and the committee had little expectation that the marketplace, the malpractice system, and the professional societies could, by themselves, weed out incompetent practitioners and ineffective procedures. Further the committee noted that most States now regulate ionizing radiation to some degree and it seemed unlikely that they could all be convinced to follow this alternative. This approach would be unwieldy, as the existing federal regulatory structure for radiation control of non-medical applications would continue unchanged.

C State Regulation Only

This Alternative would eliminate NRC control of medical uses of byproduct material and would give regulatory authority to the States. Under this alternative, byproduct materials would be regulated the same way x-ray machines, linear accelerators, pharmaceuticals and other medical devices and materials are currently regulated. Under this alternative, Federal agencies would still have a number of responsibilities; FDA would continue to regulate safety and efficacy of radiopharmaceuticals and radiation devices, DOT would continue to regulate the transportation of byproduct material, and NRC would license the manufacture of byproduct material. The committee noted that this alternative would permit States to choose the laissez-faire approach. However, the committee expected that under this Alternative, the CRCPD would encourage States to adopt its Suggested State Regulations for Control of Radiation (SSRCR).

The committee found the positive aspect of this Alternative to be the assumption that all States with existing programs would continue and expand them based on the SSRCR and thus reinforce the movement toward greater uniformity. The committee found negative aspects to be that it had no

assurance that States want this responsibility, that not all States currently have strong regulatory programs in place for NARM and machine-produced radiation, and that some State legislatures might be responsive to strong antiregulatory interest groups. The committee also felt that the lack of Federal leadership under this Alternative would make it difficult to encourage States to adopt CRCPD guidelines and that States might abandon the radiation safety programs now in place without the incentive from a Federal agency to continue operating them.

D State Regulation with Federal Guidance

This Alternative modifies Alternative C by identifying a Federal Agency, other than the NRC, to exercise a leadership role in the radiation safety community, with DHHS as a suggested agency. This is the committee's preferred Alternative.

As the committee has developed this Alternative, the Federal agency would assist in developing recommended State laws and regulations for all ionizing radiation in medicine. It could work with CRCPD to enhance the existing SSRCR and promote their adoption. The committee felt that development of guidelines through a collaborative process with the Federal agency, the States, the CRCPD, and professional organizations would result in successful implementation by all participants. Additional functions of the Federal Agency could include assisting States, investigating crises, educating the public, collecting risk data, conducting research, and monitoring the effects of shifting responsibility for regulating radiation in medicine to the States.

Under this Alternative, States would have to establish a regulatory program that includes byproduct material. Since, under this Alternative, the NRC and Agreement States would continue to regulate the manufacture of byproduct material, manufacturers would not be able to distribute byproduct material to their users unless the users were licensed by their States. Consequently this requirement would provide an inducement to States to expand or revise their existing radiation control programs to include byproduct material. Federal facilities would be encouraged to either expand their existing procedures for NARM to include byproducts or adopt the SSRCR for byproduct material.

The committee found several positive aspects of this Alternative. It includes the advantages of Alternative C, State Regulation Only, with the additional advantage of a Federal agency to provide non-regulatory oversight and leadership. The committee would expect the Federal agency to assume a leadership role for the Federal government as a whole. In addition, this Alternative would ensure that a State would be required to have a regulatory program for byproduct material for that material to be used in the State. The

committee found negative aspects of this Alternative to be the costs of the Federal agency, and that the agency could not guarantee either the quality of any State program or the safety of ionizing radiation in,medicine.

E State Regulation with Reserve Federal Authority

This Alternative would go beyond Alternative D, State Regulation with Federal Guidance, and empower the Federal agency identified in that Alternative to exercise regulatory authority over any State unwilling or unable to enact a regulatory, structure that encompasses ionizing radiation in medicine.

This Alternative would be identical to Alternative D, with the exception that if a State did not have a radiation control program it would become subject to the regulations for byproduct material devised for Federal medical centers. The Federal agency would enforce its authority only if the State did not assume any responsibility to adequately protect public health and safety. This authority would be analogous to the NRC's present authority to resume regulatory control over an Agreement State.

The committee found this alternative to have all of the positive aspects of Alternatives C and D, with the advantage that placing DHHS in the leadership role would, in the committee's view, yield more reasonable regulations if they are needed. The committee found negative aspects to be the need to set minimum standards for State programs and the need to assess those programs. This would have the effect that all States would become similar to NRC's present Agreement States. The committee was also concerned about funding, and Federal authority over what it expected to be a minority of States.

F Centralized Federal Regulation

This Alternative would make a Federal agency responsible for regulating medical uses, not only of byproduct material, but of NARM and machine-produced radiation as well. The Alternative would federalize regulation of all ionizing radiation in medicine, including standard-setting, licensing, and inspection. If this Alternative were to be adopted, the committee would recommend centralization within DHHS rather than NRC because the committee considered it best suited to administer public health programs and because it already has various levels of authority over ionizing radiation in medicine. If NRC were to be the lead federal agency, its legislative authority would need to be expanded beyond byproduct materials.

The committee found positive aspects of this alternative to include promotion of uniformity in regulation of radiation in medicine, provision for States who do not want responsibility for radiation control programs, and the development of national standards. The committee noted that the positive aspects of the Federal role described in Alternative D, State Regulation with Federal

Guidance, also apply to this Alternative. The committee found negative aspects to include the increased Federal costs of such a role, and the difficulty in achieving uniformity due to the regulatory involvement of a number of Federal agencies (DOT, EPA, OSHA) in addition to the committee's proposed DHHS. Finally, the committee noted that since NRC would continue to be responsible for the non-medical uses of byproduct material, it would be necessary for NRC and DHHS to work very closely together to avoid inconsistencies.

G Health Finance Agency

This Alternative would place regulatory authority for all health care into a single, centralized agency to counter inconsistency and inefficiency. The new agency would acquire the regulatory power now held by the medical components of the NRC and by parts of DHHS. The agency would have the power to regulate health care, broadly eliminating practices that were shown not to be effective or beneficial. The committee considered this Alternative an extreme approach for addressing a very specific issue and recognized that it had not been developed to its full logical extent. The committee considered an advantage to this approach is that it could improve minimal standards and define the goals of safety and high quality care. However, such a centralized system would mean a large increase in bureaucracy and reduce provider incentives and responsibility.

3) Assessment of Alternatives

The committee documented its consideration of the above alternatives by examining the extremes and moving toward its preferred alternative. It rejected Alternative A, Continue the Existing Situation, because it did not address the committee's concern that all ionizing radiation in medicine be administered and regulated more consistently. It rejected Alternative B, Laissez-Faire, because many committee members were not convinced that the marketplace, the malpractice system, and the professional societies could, by themselves, weed out incompetent practitioners and ineffective procedures. The committee rejected Alternative G, Health Finance Agency, because it was an all-encompassing and overwhelming solution to a very specific problem. The committee rejected Alternative F, Centralized Federal Regulation, because from a cost-benefit perspective the committee as a whole saw little reason to pursue this alternative. Thus the committee focussed on Alternatives C, State Regulation Only, D, State Regulation with Federal Guidance, and E, State Regulation with Reserve Federal Authority.

While the committee found Alternative C, State Regulation Only, attractive, it was concerned that State regulation evolve with technical advances, that Non-Agreement States be assisted in any transition from NRC regulation, and that information sharing be enhanced, so it rejected this alternative. The

committee found that Alternative E, State Regulation with Reserve Federal Authority, could result in a program very much like NRC's present Agreement State program which would not resolve the committee's concerns about that program's funding characteristics and practical drawbacks. The committee therefore arrived at its preferred choice, Alternative D, State Regulation with Federal Guidance.

As discussed above, Alternative D would give regulatory authority over medical uses of byproduct material to the States. The States would expand their existing radiation control programs that apply to NARM to include byproduct material as well. The committee recommends that a Federal agency, DHHS, exercise a leadership role in the radiation safety community. The leadership role would be non-regulatory and would assist in developing recommended state laws and regulations, acting as an information clearinghouse, and distributing resources for training and research. The Federal agency would work in conjunction with the CRCPD and other professional organizations to develop recommended state laws and regulations for all ionizing radiation in medicine. The NRC would retain responsibility for the manufacture and distribution of byproduct material (including sealed sources and devices) used in medicine. Further, NRC would condition these licenses to require that products could only be distributed to users who were licensed by a State.

IV IOM REPORT - RECOMMENDATIONS

To implement its preferred alternative, the committee made a total of eight specific recommendations; two to Congress, three to the NRC, and three to the CRCPD and States. First, the committee recommended that Congress: 1) eliminate all aspects of the NRC's medical use program to include 10 CFR Part 35 and applicable activities conducted under 10 CFR Part 20; and 2) direct the Secretary of Health and Human Services to support, coordinate, and encourage activities involving regulation of all ionizing radiation in medicine including support the operation of the CRCPD, assist States in implementation of regulations, oversight of State programs, enhance training and standards for health care personnel, and investigate future significant radiation medicine incidents.

The recommendations to the NRC were to: 1) immediately relax enforcement of 10 CFR 35.32 and 35.33; 2) if Congress fails to act within 2 years to the committee's recommendations above, initiate formal steps under the Administrative Procedures Act to revoke 10 CFR Part 35 in its entirety; and 3) separate the costs of formulating regulations from costs of administering those regulations.

The recommendations to the CRCPD and the States were to: 1) incorporate into the SSRCR any relevant concepts from 10 CFR Part 35; 2) enact legislation to incorporate the regulation of reactor-generated byproducts into existing state

regulatory programs; and 3) continually reevaluate regulations and procedures to ensure congruence with evolving scientific understanding of radiation bioeffects and associated risks and benefits.

The committee did not reach total unanimity on the final recommendations. A committee member stated that federal regulatory authority should be reformed, not repealed. This dissenting opinion is included as a separate Appendix to the report.

The following sections discuss the recommendations individually. Each section contains a brief description of the recommendation, a summary of the committee's rationale for the recommendation, the NRC staff's principal concerns, and some pertinent public comments.[4]

A RECOMMENDATIONS TO CONGRESS

A1. *The committee recommends that Congress eliminate all aspects of the NRC's Medical Use Program, 10 CFR Part 35, and those regulatory activities conducted under 10 CFR Part 20 that are applicable to medical uses.*

DESCRIPTION

By this action, Congress would relinquish responsibility for regulation of byproduct material used in medicine to each state. NRC would retain regulatory authority over manufacturers of byproduct material used in medicine. Other federal agencies, such as the FDA, the DOT, and the EPA, would retain their regulatory authority over radiation.

IOM RATIONALE

The intensity with which the byproduct area of radiation medicine is being regulated at the federal level far exceeds the rest of ionizing radiation used in medicine and most of the rest of medical practice and has little if any justification. In fact, the concentration of resources spent to reduce adverse events involving byproduct material, although seemingly effective, appears to have gone beyond the point at which the additional dollar spent on regulation achieves an equivalent dollar benefit.

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[4] A list of commentors organized by commentor affiliation, a list of commentors by general view, and a summary of specific comments appear in Appendices 1, 2 and 3, respectively.

All ionizing radiation, with the exception of byproduct material, is currently regulated or subject to regulation at the State level. States have the ability to regulate radiation effectively. Although the committee cannot guarantee that states will effectively regulate byproduct material, it believes they will. Further, States with insufficient resources could join a consortium of states for the purposes of implementation and oversight.

Rescission of authority at the federal level for regulation of the medical use of byproduct material has three benefits: 1) it eliminates prescriptive and costly regulations that yield marginal risk reduction; 2) it shifts responsibility, by giving state governments authority over the health and safety of their citizens; and 3) it promotes uniform treatment, in that radionuclides and machine-produced radiation are regulated by a single level of government at equal intensity, regardless of their source.

NRC STAFF ISSUES

1. The committee recognizes that not all states currently have strong regulatory programs in place for NARM and machine-produced radiation. In fact, not all States currently regulate ionizing radiation used in medicine. What assurance does the committee, or Congress or the NRC, have that all States will assume the responsibility for medical use of byproduct material?

2. This recommendation assumes that federal facilities will expand the scope of their existing regulations to cover all ionizing radiation in medicine - what existing regulations currently apply to federal facilities (other than those of the NRC)?

3. How would the goal of "uniform treatment" and regulation by a single level of government at "equal intensity" be achieved through legislation and rulemaking giving responsibility to the States.

PUBLIC COMMENTS

NRC has received 47 comments on the committee's report. About one third of the commentors support this recommendation and the rest of the committee's recommendations as well. These commentors included the Department of Veteran's Affairs, several State agencies, four professional societies associated with the use of radiation in medicine and six individuals. Several of these commentors not only supported this recommendation, but believed that NRC should discontinue all of its regulation of byproduct materials, and give that responsibility to the States.

A second third of the commentors supported the concept of regulatory reform, but with retention of Federal authority. These commentors included three Federal agencies, three professional societies involved in radiation in medicine, 10 States and NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI). Nine of these commentors favored continued regulation by the NRC, eight were not specific on which Federal agency should have authority, and two, the State of California and the ACMUI would vest authority with DHHS.

Four commentors, including the State of New Jersey favored regulatory reform, but only after additional analysis.

Nine commentors supported the concept of uniform regulation for all radioactive materials, including NARM, with Federal oversight.

Several specific comments are of interest. The EPA felt that the report reflected the concerns of the regulated community more than those of the public at large. The Department of Defense indicated that the Federal regulatory authority over medical use of byproduct material should be reevaluated and perhaps relaxed and restructured, but not abolished. The States of Utah and Virginia were concerned that State legislatures might view this as an unfunded mandate and would need additional Federal support. The CRCPD does not support the recommendation. "CRCPD is concerned that elimination of the entire program, as recommended, could have immediate and undesirable consequences on citizens in non-Agreement States which cannot or will not have developed a state program consistent with the national model prior to Congressional action. In addition, the absence of federal authority in the medical use area may also have long term consequences for Agreement States as they try to maintain a nationally consistent program in the face of budget cutbacks and a changing regulatory philosophy."[5] Several non-Agreement States indicated that they had neither the resources nor the capability to develop a program to adequately protect public health and safety.

A2. *Congress direct the Secretary of Health and Human Services to support, coordinate, and encourage the following activities involving regulation of all ionizing radiation in medicine:*

a. supporting the operation of the CRCPD;
b. providing a venue for the review and evaluation of Suggested State Regulations for Control of Radiation;

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[5] CRCPD position on the NAS report, reached at their meeting in Albuquerque, New Mexico, on May 8, 1996

c. assisting states in implementation of their regulations;
d. aiding in assessment of the effectiveness of state programs through the collection and analysis of data;
e. helping develop survey methods by which the rate of adverse events for a wide range of procedures and devices might be measured;
f. monitoring the effects of deregulation;
g. enhancing training and standards for health care personnel; and
h. investigating future significant radiation medicine incidents.

DESCRIPTION

In addition to the above, DHHS would educate the public for the primary purpose of "... putting radiation risk in a more accurate and balanced perspective." Adverse events for investigational drugs and blood products must be reported to FDA as are adverse events involving radiation devices resulting in serious injury or death.

As noted in the previous recommendation, NRC and Agreement States would continue to regulate the manufacture of byproduct material for use in radiation devices and radiopharmaceuticals; thus manufacturers would not be able to distribute radioactive byproduct material to users unless they were licensed by their states.

IOM RATIONALE

A Federal agency, such as DHHS, would assist states to establish regulatory programs; train state radiation control personnel; build liaisons between smaller states that wish to share regulatory systems; develop survey methodology; and monitor the success of regulatory programs.

DHHS has an extensive history in regulating radiation in medicine. Within DHHS, FDA exercises direct authority to determine the safety and effectiveness, and to approve the marketing, labelling, and manufactur of all radiation products used in medicine. FDA has promulgated regulations establishing quality control standards and a certification program for medical facilities that provide mammography services. FDA has issued guidelines and recommendations regarding public exposure to ionizing and non-ionizing radiation.

The NRC should not regulate the education and training of health care personnel - it should be done by professional organizations and by the states.

NRC STAFF ISSUES

1. Would DHHS have any regulatory responsibility for Federal facilities other than the Public Health Service? If not, who would have authority over Federal facilities?

2. Current reporting requirements for FDA are not identical to those of NRC - they only require reporting adverse events resulting in serious bodily injury (to manufacturer) or death (to FDA). There are no reporting requirements for radiopharmaceuticals other than investigational drugs except on a voluntary basis. To what extent should administration errors be reported?

3. In view of the overall reduction in federal spending, whether DHHS would be provided any appropriations to carry out these additional responsibilities cannot be predicted. With the reduction in federal spending and with the knowledge that the NRC is supported by user fees rather than taxpayer dollars, would Congress appropriate sufficient funds for even the minimal expenses of this agency?

4. How would the effects of deregulation be monitored? The report states that the committee did not possess the requisite expertise to address the issue of appropriate criteria for measuring the effectiveness of regulatory programs.

PUBLIC COMMENTS

As mentioned above, about a third of the commentors support this recommendation along with all the committee's recommendations. A number of commentors support the role of a Federal agency described in this recommendation, but do not necessarily endorse DHHS. Many of these latter commentors believe that the Federal agency should have at least some authority and that it should be responsible for at least NARM as well as byproduct material. The CRCPD view is illustrative. CRCPD supports the concept of a single federal agency with a strong leadership role, and believes that consolidation of authority presently found in several agencies including NRC, DHHS, OSHA, and EPA is very desirable. However, CRCPD, in addition to several states, do not support the automatic selection of DHHS as the lead agency, but consider that radiation protection should be a major responsibility of the lead agency. The OAS[6] recommended a revision to recommendation A2 to include that a single federal agency should be directed (by Congress) to support, coordinate, and oversee specified activities involving regulation of all ionizing radiation in medicine. The OAS did not reach consensus on which agency should have the responsibility.

The agency most affected by this recommendation is DHHS, who does not support it. DHHS does not find the committee's arguments compelling and does not consider the legislation recommended by the committee likely. Further, in the

[6] The OAS comment provided the recommendations of and consensus reached at a NRC and Agreement State technical workshop conducted on March 6, 1996.

event of such legislation, DHHS considers the probability low that it would receive funding from Congress commensurate with its additional responsibilities.

B RECOMMENDATIONS TO THE NRC

B1. *The NRC should immediately relax enforcement of 10 CFR 35.32 and 35.33 through its present mechanisms.*

DESCRIPTION

NRC's 10 CFR Part 35.32, Quality Management Program, requires, among other things, that medical licensees have written procedures to ensure that direction for a therapeutic administration is made in writing, that the patient's identity is verified by more than one method, that unintended deviation from the written directive is evaluated, and that the licensees review this program at least once every 12 months.

NRC's 10 CFR Part 35.33, Notifications, Reports, and Records of Misadministrations, requires, in part, that medical licensees notify the NRC within one calendar day of the discovery of a misadministration, and that they submit a written report within 15 days, and that they retain a record of each misadministration for five years.

The information required by 10 CFR 35.33 would not be entirely abandoned. NRC could continue to cooperate with the FDA as provided in their MOU to obtain data on devices, drugs, and biological products that relate to device malfunction, serious injury, or death.

IOM RATIONALE

NRC's Quality Management (QM) rule lacks the basic elements of a QM program: comprehensive process and outcomes data, feedback mechanisms for health care providers, education of clinicians to achieve continuous improvement, and follow-up measurement to monitor change/improvement.

The regulation of byproduct material greatly exceeds the regulation of chemotherapy, surgery, anesthesia, and the use of general pharmaceuticals except for controlled substances, all of which are unregulated at the federal level.

A lower rate of adverse incidents in radiation medicine is not a result of stricter regulatory oversight. The more detailed reporting and enforcement systems required for byproduct materials do not seem to result in even a marginal decrease in risk to providers, patients, or members of the public.

The level at which the NRC currently enforces 10 CFR 35.32 and 35.33, through detailed and voluminous documentation, reporting, and penalties, is inconsistent with the NRC's Medical Policy Statement, which favors minimum regulatory intrusion into the practice of medicine.

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has a performance standard which requires intensive assessment when performance varies from recognized standards, but does not specifically require reporting of medication errors except in accordance with written procedures of the hospital.

Elimination of the QM rule would not lessen the radiation protection of the public, occupational worker, or the patient.

The regulated community has expressed reservations about seeking advice from the NRC, fearing that they might become the target of punitive reprisals.

When the NRC levies a fine, the agency also issues a press release describing the violation and the fine. Licensees assert that adverse economic impact of such press releases is considerable.

NRC STAFF ISSUES

1. The lack of data for comparing byproduct material, NARM and machine-produce radiation limited the scientific basis of the committee's findings. How can we achieve improved data collection on actual incidence and rates of adverse incidents and misadministrations? Is there a need for improved databases?

2. What is the rationale or basis for the necessity for immediate action?

3. Assuming that NRC were to immediately relax enforcement, NRC would be in the position of having a regulation for which there would have been no monitoring or enforcement. If NRC were to follow this recommendation, what followup actions should NRC conduct in the event of a misadministration resulting in serious injury or death?

4. If NRC lacked statutory or regulatory authority governing the medical and biomedical research use of byproduct material, why should NRC continue to gather data on user errors, drugs, and biological products to share with FDA under the MOU (unless reimbursed by another Federal agency)?

PUBLIC COMMENTS

A number of commentors supported the concept that many of, NRC's requirements are overly prescriptive and burdensome. CRCPD supports relaxation of these requirements because it finds them overly prescriptive and unnecessarily burdensome. The Organization of Agreement States believes that NRC should immediately relax enforcement of these requirements, and further considers that the Quality Management Rule should not be an item of Agreement State compatibility.

B2. *The committee recommends that the NRC initiate formal steps under the Administrative Procedure Act to revoke Part 35 in its entirety, if Congress fails to act within two years in response to the two recommendations to Congress stated above.*

DESCRIPTION

NRC's 10 CFR Part 35, Medical Use of Byproduct Material, contains technical and administrative requirements that apply specifically to medical applications. It sets quality management and reporting requirements, and establishes training and experience criteria for users of byproduct material. It sets requirements including dose calibration, leak testing, source inventory, patient release, instructions to nurses, and survey requirements as well as use of syringe shields and storage of waste for decay.

IOM RATIONALE

In addition to NRC's overly stringent enforcement, the regulations themselves are excessive and duplicative. 10 CFR Part 35 covers areas that either are already regulated at the institutional level or are best left to the states, to professional societies, and to patients in consultation with their doctors.

States regulate the medical uses of other forms of ionizing radiation and, could easily fold byproduct material into their regulatory programs.

The CRCPD could add byproduct material to its suggested state regulations. These additions could incorporate relevant concepts currently in Part 35.

Doctors have ethical obligations, codified in professional standards, for informing patients of medical errors. The relatively low misadministration rate could be maintained by less stringent programs that are administered at the state level by professional societies, and by existing liability law.

The FDA collects data on adverse effects of radiopharmaceuticals and incidents of failure of radiation-emitting medical devices, and it could assume the monitoring responsibilities of the NRC.

Public safety in the medical use of ionizing radiation would yet exist in the fact that the NRC would still retain responsibility for the licensing of manufacturers and, consequently could ensure that byproduct material was withheld from any state that failed to license users and regulate the use and safety of byproduct material.

The committee strongly endorses the formal route of notice and comment rulemaking, subject to the Administrative Procedure Act, to accomplish the rescission of all of Part 35.

NRC STAFF ISSUES

1. This recommendation presupposes Congress will not act, and therefore will not vest DHHS with a leadership role. This could result in the laissez faire or state control regulatory structures, both of which were rejected by the committee. How would this recommendation achieve the goal of the preferred alternative?

2. With the lack of data cited in the report, on what scientific basis might NRC make a finding that there is no unreasonable risk to public health and safety, and thereby exempt medical use of byproduct material from the requirements of a license, as set forth in Section 81 of the Atomic Energy Act?

PUBLIC COMMENTS

Many commentors, to include professional organizations, State agencies, and individuals, were in favor of the need to revise Part 35. While CRCPD considers that a major revision to 10 CFR Part 35 is needed, it does not support this recommendation. OAS believes that 10 CFR Part 35 should be revised significantly, but that it should not be revoked in the absence of legislation. OAS believes that a minimum level of radiation protection must be available.

B3. *The committee recommends that the NRC separate the costs of formulating regulations from the cost of administering those regulations.*

DESCRIPTION

The Omnibus Budget Reconciliation Act of 1990 requires NRC to recover 100% of its budget by charging fees to NRC applicants and licensees. As a result, NRC licensees bear all of the agency's costs both of developing its regulations and of administering them. Separating these costs would enable NRC to recover development costs from its licensees differently than it recovers its administrative costs.

IOM RATIONALE

Only NRC-licensed institutions should bear the NRC's costs of licensing and inspection, whereas the costs of developing standards should be borne by all institutions, whether or not they are located in NRC-regulated states.

Licensing fees charged to health care facilities to meet the cost of the existing NRC program are becoming more expensive as more states become Agreement States.

Several individuals interviewed during site visits voiced concern that excessive costs force laboratories to stop using radionuclides, which in turn delays or prohibits the development and implementation of new uses of radionuclides in medicine.

NRC STAFF ISSUE

If NRC were to separate the costs of formulating regulations from the cost of administering these regulations, how would the Agreement State licensees bear the cost of developing standards?

PUBLIC COMMENTS

CRCPD supports this recommendation and recommends that Congress provide general funds to support development of essential regulatory standards. OAS identified the issue of how Agreement States would bear the costs of developing standards if NRC were to accept this recommendation.

C RECOMMENDATIONS TO THE CRCPD AND THE STATES

C1. *The committee recommends that the Conference of Radiation Control Program Directors incorporate into its Suggested State Regulations for Control of Radiation any relevant concepts from 10 CFR Part 35 that are not already integrated in those suggested regulations.*

IOM RATIONALE

All states will be able to provide regulatory oversight for AEA material in a manner similar to that provided for non-AEA material through the adoptions of CRCPD's Suggested State Regulations for the Control of Radiation. "[T]he committee expects that byproduct materials can be accommodated in the state systems."

Although State laws, regulations, and administrative practices vary, States can and do achieve a level of uniformity in many areas through cooperative, voluntary, and informal arrangements.

Although States cannot be compelled to accept the voluntary guidelines or the SSRCR, a variety of forces can greatly influence them to do so such as a collaborative effort, professional peer pressure, consumer groups and the media, and State medical societies.

CRCPD will continue to provide SSRCRs of the current level of quality without the assistance of the NRC, but with another federal agency providing "voluntary guidelines and model regulations for states"

NRC would continue to fund the CRCPD's efforts with respect to all nonmedical uses of byproduct material.

NRC STAFF ISSUES

1 Will the states voluntarily adopt the CRCPD's SSRCR in the absence of any real compelling mandate placed on either CRCPD or the states? For example, in the case of the recently passed mammography law, Congress provided a compelling reason for hospitals and clinics to meet the quality standards: i.e., in order to be reimbursed for mammography services, the hospital or clinic must be certified as meeting the standards.

2 The level to which the states currently adopt the SSRCR varies from state to state. Would there be greater uniformity under the proposed recommendation?

PUBLIC COMMENTS

CRCPD considers that it already has accomplished this.

C2. *The committee recommends that all state legislatures enact enabling legislation to incorporate the regulation of reactor-generated byproducts into existing state regulatory programs.*

IOM RATIONALE

States have effectively regulated naturally-occurring and NARM in the past and continue to do so. Therefore all States can regulate the medical use of byproduct material effectively.

Congress will modify the AEA to revoke the NRC's authority to regulate the medical use of byproduct material, give another Federal agency the responsibility for providing guidance, and allow all States, at their option, to exercise regulatory authority over the medical use of byproduct materials.

All States will devote the additional necessary resources to provide adequate protection of the public health and safety related to the medical use of byproduct materials with "little", if any, additional federal funding.

The possibility of precluding users from obtaining byproduct material from manufacturers in those "states that did not include byproduct material into their existing regulatory programs" would be acceptable to Congress and the public.

NRC STAFF ISSUE

Will all States in fact have the will, the resources, and the competence to regulate the medical use of all sources and uses of ionizing radiation safely?

PUBLIC COMMENTS

OAS endorses this recommendation, but as applied to all ionizing radiation. CRCPD endorses the recommendation, although it recognizes that not all States will choose to establish comprehensive programs that include byproduct materials. However, the CRCPD continues to support consistent application of radiation protection standards nationwide and believes that this can be best accomplished by having all radiation programs in a single state agency which can deal comprehensively with all forms of ionizing radiation within the state.

C3. *The committee recommends that the Conference of Radiation Control Program Directors and the states continually reevaluate their regulations and procedures pertaining to radiation medicine to ensure congruence with evolving scientific understanding of radiation bioeffects and to be in accord with advances in knowledge regarding benefits and risks related to medical and biomedical research uses of ionizing radiation in medicine.*

IOM RATIONALE

Continual reevaluation and maintaining congruence is a necessary step for providing adequate protection of the public health and safety.

The CRCPD and all states will devote the necessary resources to maintain congruence with evolving scientific understanding of radiation bioeffects and be in accord with advances in knowledge regarding the benefits and risks of the medical use of ionizing radiation.

NRC STAFF ISSUE

Many states have adopted regulations for non-AEA materials that are similar to those that NRC implements for AEA materials and requires Agreement States to adopt as items of compatibility (e.g., NRC's QM rule for cobalt teletherapy versus State regulations for accelerator teletherapy). Will the CRCPD be able to effectively "ensure congruence" of the States' regulations and procedures to "be in accord with advances in knowledge regarding benefits and risks ..." by using voluntary mechanisms in the absence of the regulatory presence and resource support of NRC?

PUBLIC COMMENTS

Both OAS and CRCPD endorse this recommendation.

V NRC ACTIONS AND COMMENT SUMMARY

A NRC Actions to Date

The IOM provided NRC with a prepublication copy of the committee's report in December 1995. The NRC provided copies of the report to all Agreement States and non-Agreement States and Territories, appropriate Federal agencies, CRCPD, OAS, Congressional Oversight Committees and NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI). In addition, the NRC published a Federal Register notice (61 FR 1648) on January 22, 1996, and issued a press release acknowledging receipt of the report and requesting comments on the possible impacts of the report, to include any views on policy, legislative, rulemaking, and guidance issues. The Commission directed the staff to consider the report and comments received within its Strategic Assessment and Rebaselining efforts. While the report is being considered, the NRC is continuing to implement the ongoing medical use program.

Several public meetings have been held to discuss the report. The ACMUI met on February 21-22, 1996 and subsequently briefed the Commission on May 3, 1996 to discuss their recommendations. Briefly, the ACMUI did not recommend any of specified alternatives. They reached consensus that the medical use regulatory program should be rebuilt, reassessing the objectives of the regulations and encompassing all uses of ionizing radiation in medicine, and that States should be federally mandated to administer the program, with appropriate incentives to encourage States to comply. State programs should be monitored by a Federal agency with an overall medical use perspective (e.g., DHHS).

The OAS and the members of the IOM committee briefed the Commission on February 26 and 27, 1996, respectively. In addition, the report was discussed at a joint NRC and Agreement State technical workshop on March 5-6, 1996. The workshop included representatives of 18 Agreement States and two non-Agreement States. More recently, the report was discussed with the Conference of Radiation Control Program Directors on May 6, 1996.

B COMMENTS ON IOM REPORT

As of the end of August 1996, the staff had received 47 written comments on the report. The two major categories of responses are either in support of, or opposition to, the overall recommendations of the IOM committee. However, within each of these major categories, there are subsets with respect to the specific direction or focus of the comments. None of the comments received specifically indicated that there should be no Federal involvement.

The Secretary of the Department of Health and Human Services (DHHS), the Federal agency that would be most directly affected by the IOM recommendations, indicated that the report does not make a compelling public health agreement for DHHS to assure the recommended new role. Furthermore, DHHS raised a concern that Congress would not provide resources commensurate with the added responsibilities.

The majority of comments received (32 out of 47) did not endorse the full range of recommendations put forth by the IOM committee. Four of the 15 respondents that supported the recommendations indicated that the recommendations should encompass all uses of byproduct materials. The Department of Veterans Affairs, in its support of the IOM report, indicated that legislative initiatives should ensure that Federal facilities are not subject to State and local regulations.

The comments that did not support all the IOM recommendations varied dramatically in the focus of their viewpoints and opinions. The degree of regulatory reform perceived to be necessary ranged from simply recognizing the

merits of the issues raised by the IOM committee to a need for a complete restructuring of the regulatory program. The non-Agreement States that responded were particularly concerned about the substantial financial impact of the recommendations and the issue of this being, in effect, an unfunded Federal mandate. For example, as indicated in the response from Hawaii, public health and safety could be jeopardized in those States with insufficient resources or capability to adequately implement the regulation of byproduct materials. The Department of Defense response, which summarized the responses from the three Service Medical Departments (Army, Navy, and Air Force), supported the need to re-evaluate the current regulatory structure, but emphasized the need for a uniform regulatory authority. There were several responses that recommended the need for Federal oversight for all uses of radiation.

The Organization of Agreement States response provided a summary of the consensus of the participants of the NRC and Agreement State technical workshop conducted March 5-6, 1996, which included that all radiation use (medical and non-medical uses) should be consolidated under one Federal agency. The CRCPD prepared a position paper, which supported the leadership role of a single federal agency for all forms of ionizing radiation, at their May 6 meeting. The comments of these organizations are summarized above under the specific recommendations to which they apply.

The NRC will continue to evaluate comments as part of the strategic assessment and rebaselining efforts. A summary of the comments is provided in Attachments 1-3.

Categories of Responses Received on IOM Report

Federal Agencies:

Department of Defense (DOD) - consolidates views for three services
Department of Health and Human Services (DHHS)
Department of Labor, Occupational Safety and Health Administration (OSHA)
Department of Veterans Affairs (DVA)
Environmental Protection Agency (EPA)

Agreement States:

Arkansas
California
Florida (Office Radiation Control) - R
Florida (State Health Office) - H
Illinois
Kentucky
Maryland
New Mexico
New York (Dept. Environmental Conservation) - E
New York (Dept. Health) - H
New York (Dept. Labor) - L
Tennessee
Texas
Utah
Vermont
Washington

Non-Agreement States/Territories:

Alaska
American Samoa
Delaware
Hawaii
Massachusetts
New Jersey
Virginia
Wyoming

Organizations/Committees:

American Association of Physicists in Medicine (AAPM)
American College of Cardiology (ACC)
American College of Medical Physics (ACMP)
American College of Nuclear Physicians/Society of Nuclear Medicine (ACNP/SNM)
American College of Nuclear Physicians - California chapter (ACNP-CA)
American College of Radiology (ACR)
American Pharmaceutical Association (APhA)
American Society of Nuclear Cardiology (ASNC)
Conference of Radiation Control Program Directors (CRCPD)
NRC's Advisory Committee on Medical Uses of Isotopes (ACMUI)
Organization of Agreement States (OAS)[7]

Other Respondents:

CBeasley, St. John's Regional Health Center, Springfield, MO
MHafermann, Virginia Mason Cancer Center, Seattle, WA
DJones, Northwest Medical Physics Center, Lynnwood, WA
CMarcus, University of California, Los Angeles, CA
CPerez, Washington University, St. Louis, MO
GPoteat, OH
JRieke, Virginia Mason Cancer Center, Seattle, WA
DSchumacher, Northwest Medical Physics Center, Lynnwood, WA
MSelikson, RSO, University of Pennsylvania, Philadelphia, PA
St. John's Hospital, Jackson, WY

[7] The OAS comment provided the recommendations of and consensus views reached at the NRC and Agreement State Technical workshop. The session on the NAS report included representatives from 18 Agreement States (CA, NY, SC, NV, IL, WA, TX, MS, TN, GA, NE, CO, KY, KS, NYC, FL, AR, AZ) and two non-Agreement States (OH, PA).

General Comments on IOM Report

Respondents in favor of IOM recommendations:

Support IOM report/recommendations as written:

AAPM
ACNP/SNM
ASNC
DVA
NM
MHafermann (Virginia Mason Cancer Ctr)
DJones (Northwest Medical Physics Ctr)
CMarcus (UCLA)
CPerez (Washington Univ)
JRieke (Virginia Mason Cancer Ctr)
DSchumacher (Northwest Medical Physics Ctr)

Support IOM report/recommendations, but as applied to all materials:

FL (R)
NY (H)
NY (L)
ACNP-CA

Respondents not in agreement with IOM recommendations:

Support concept of regulatory reform[8] but retain Federal authority[9]:

DHHS oversight: ACMUI, CA

NRC oversight: EPA, ACMP, ACR, HI, KY, NY(E), UT, WA, GPoteat(OH)

Unspecified oversight: DHHS[10], DOD, ACC, AK, DE, TN, VA, WY

Support concept of regulatory reform, but after additional analysis:

CBeasley (St John's Regional Health Center)
MSelikson (RSO, Univ. of Pennsylvania)
NJ
St. John's Hospital

Support concept of uniformity for all radioactive materials regulation with Federal oversight:

CRCPD
OAS
APhA
AR (NRC as lead agency)
FL (H)
IL
MA
MD
TX

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[8] It should be pointed out that the degree of regulatory reform perceived to be necessary by different respondents varied from recognizing the concerns raised by the IOM to a drastic change in the approach to regulation of medical uses.

[9] Some States (e.g., VA, WY, DE) were primarily concerned with the substantial financial impact of the NAS recommendations and the issue of unfunded Federal mandates, rather than more specific concerns on the overall approach for regulation.

[10] DHHS did not address the issue of regulatory reform, Federal authority, or concerns raised by the IOM, but focussed on the implications of the recommendation to DHHS.

Respondents indicating report under review

DOL
AS
VT

Specific Comments on IOM Report

Category of Response	Respondent	Specific Comments
RESPONDENTS IN AGREEMENT WITH IOM RECOMMENDATIONS		
Support IOM report/ recommendation as written	DVA	The Veterans Health Administration generally concurs with and endorses the findings and recommendations of IOM. Principal concern is lack of specifics regarding regulation of Federal entitities and also the regulation of medical research programs.
	New Mexico	Agrees with IOM recommendation that Congress remove regulation of possession and use of material subject to AEA from NRC's purview. Supports leadership role of DHHS so long as all states maintain regulatory programs that measure comprehensive standards of performance and effectiveness.
	AAPM	AAPM fundamentally supports position, conclusions, and recommendations of the IOM report. NRC should be removed from its current regulatory role for medical use. Establish programs for implementing States' regulations monitored by appropriate Federal health agency with assistance of user community and professional organizations.
	ACNP/SNM	The ACNP and SNM believe the report proposes a sound and thoughtful approach to the regulation of nuclear medicine and urges NRC to implement the IOM recommendations, allowing for comment on specific means to achieve implementation.
	ASNC	Concur with the IOM's conclusions and support their recommendations for a uniform policy to be set at Federal level which can be enforced by the States. DHHS should include medical radiation safety as part of its health care management plan.
	MHafermann	Endorses recommendations of IOM. Does not agree with sentiments of Robert Adler in Appendix L.

Category of Response	Respondent	Specific Comments
RESPONDENTS IN AGREEMENT WITH IOM RECOMMENDATIONS		
Support IOM report/ recommendation as written	DJones	Endorses recommendations of IOM. Does not agree with sentiments of Robert Adler in Appendix L.
	CMarcus	Supports the IOM report and expresses disagreement with statements made by Robert Adler in his supplemental statement (Appendix L)
	CPerez	Expresses strong support for many of recommendations.
	JRieke	Endorses recommendations of IOM. Does not agree with sentiments of Robert Adler in Appendix L.
	DSchumacher	Supports recommendations proposed by IOM committee.
Support IOM report/ recommendations, but as applied to all materials	Florida (Rad. Control)	Support idea of delegating regulation of medical byproduct material to states in addition to all agreement materials.
	New York (Dept. Health)	Support the IOM's conclusion that the regulation of medical use of byproduct materials should be carried out at the state level. Encourages the NRC to not limit its response to the IOM report to the narrow medical focus of the report.
	New York (Dept. Labor)	Supports the IOM's recommendation that NRC discontinue regulation of medical use of byproduct materials, but considers it illogical to limit the recommendation to this one area (should include nuclear pharmacies, manufacturers, distributors, and industrial users)
	ACNP-CA	NRC's entire materials program should be given to the States and Federal entities

Category of Response	Respondent	Specific Comments
RESPONDENTS NOT IN AGREEMENT WITH IOM RECOMMENDATIONS		
Support concept of regulatory reform but retain Federal authority	ACMUI	ACMUI indicated a preference for a variant of the IOM preferred alternative in which there would be substantial Federal oversight of State programs with a mechanism to ensure compliance of States and users. State programs should be monitored by a Federal agency with overall medical use perspective (DHHS).
	DHHS	Report does not make a compelling public health argument for DHHS taking on a substantial new role. The probability is low that Congress would provide adequate resources. DHHS does not support the recommendation.
	DOD	Federal regulatory authority over medical use of byproduct material should be reevaluated and perhaps relaxed and restructured, but not abolished in favor of a voluntary or State-operated system.
	EPA	Report reflects the concerns of the regulated community more than the public at large. There may be aspects of NRC's program that can be improved, but NRC should continue to assure public is protected.
	ACC	Transfer of oversight of the medical use of isotopes to the States seems reasonable. However, strongly encourage Federal oversight of this state initiative. An obvious drawback would be if all States had separate regulations for licensure and compliance.
	ACMP	Supports the need for a drastic change in regulation of radiation in medical use including use of Advisory Panels (comprised of users, manufacturers, and public) to determine the regulatory framework to be applied uniformly in medical profession. Current regulations should be modified.
	ACR	In lieu of Congressional action to eliminate NRC's medical use program, the ACR believes that NRC's medical use program must be rebuilt and its objectives thoroughly reassessed.

Category of Response	Respondent	Specific Comments
RESPONDENTS NOT IN AGREEMENT WITH IOM RECOMMENDATIONS (continued)		
Support concept of regulatory reform but retain Federal authority (continued)	Alaska	This would not be a cost effective nor efficient reform for Alaska. It is in the best interest of the State to support the existing method of regulating nuclear medicine licensees by a Federal agency.
	California	In view of split regulatory authority at federal level and apparent reluctance of NRC to expand jurisdiction, agree that Congress remove NRC's authority. DHHS should be given authority to ensure that every state maintains a radiation program that meets minimum, comprehensive, consensus standards of performance and effectiveness.
	Delaware	The impact of the IOM recommendations would be substantial in terms of our increased need for funding, staffing, training and infrastructure requirements.
	Hawaii	Does not have resources or capability to adequately implement regulation of byproduct materials. Without assistance (training and development) to States, the removal of NRC's authority may significantly jeopardize public health and safety.
	Kentucky	A better approach would be to have NRC revise its medical program to go along with the recommendations the Institute has given in preferred alternative D.
	New York (Dept. Environ. Conservation)	Many unforeseen consequences may occur if AEA is modified. Commission should proceed cautiously in pursuing IOM recommendations that may alter the present AEA.
	Tennessee	While the findings of the Committee have some merit, there is no conclusive support provided to document them. Sweeping changes are not well thought out and may result in chaos.
	Utah	State legislatures may view this as another unfunded Federal mandate and may provide no additional support to the State program. Medical community should work with NRC, States, and other parties to resolve the regulation issue.

Category of Response	Respondent	Specific Comments
RESPONDENTS NOT IN AGREEMENT WITH IOM RECOMMENDATIONS (continued)		
Support concept of regulatory reform but retain Federal authority (continued)	Virginia	The Commonwealth is in no position to assume any additional unfunded Federal mandates. Could only assume regulatory responsibility if NRC provides funds to defray cost of implementing the program.
	Washington	NRC should focus on radiation safety of worker and non-patient public (oversight of production, distribution, and handling of byproduct materials) while protection of patient is best handled through State boards of medicine and pharmacy.
	Wyoming	The conclusions of the report neglect the considerable hardship to be incurred by smaller, less populous, and less affluent States. Only through continued Federal regulatory participation can the goals of uniformity and public access to safe medical procedures be achieved.
	GPoteat	Potential decrease in safety may result from a transfer to State regulators of NRC's authority. Minor changes are necessary but overall NRC's regulations balance the need to protect workers, patient and the public with the requirements of medical practice.

Category of Response	Respondent	Specific Comments
RESPONDENTS NOT IN AGREEMENT WITH IOM RECOMMENDATIONS (continued)		
Support concept of regulatory reform, but after additional analysis	New Jersey	If NJ chose not to become an Agreement State, public may not be assured of adequate protection. If adopting the recommendations, NRC and Congress should not act precipitously, but allow the States to prepare for assuming regulatory programs in orderly fashion.
	University of Pennsylvania	Before moving in the direction of a State-based decentralized system, a better evaluation of potential both for increased risk to the public and increased cost to the medical industry is necessary.
	St. John's Hospital	Urges NRC to give every consideration to IOM report, particularly the review of risk assessment.
	CBeasley	The report missed part of its stated intended goal to review the current system of regulation (the issues of uniformity among states was not fully explored). Proposes review in more detail the regulation of non-nuclear medicine radiology and question of uniformity between states.
Support concept of uniformity for all radioactive materials regulation with Federal oversight	OAS	At NRC/Agreement State Technical Workshop, consensus was reached that all radiation use (regulated currently under NRC, FDA, EPA, and OSHA) should be consolidated under a single Federal agency.
	CRCPD	Absence of federal authority in medical use area may have immediate and undesirable consequences on citizens in non- Agreement States and long term consequences for Agreement States trying to maintain a nationally consistent program. CRCPD does not support automatic selection of DHHS as the agency to provide leadership role.
	APhA	All ionizing radiation should be grouped together under a uniform regulation. Transfer responsibility for medical uses of any ionizing radiation to the States. Some Federal authority should remain over the medical uses of ionizing radiation (NRC or a similar federal agency).

Category of Response	Respondent	Specific Comments
RESPONDENTS NOT IN AGREEMENT WITH IOM RECOMMENDATIONS (continued)		
Support concept of uniformity for all radioactive materials regulation with Federal oversight (continued)	Arkansas	The NRC should consider alternative A2 (status quo modified). If major changes are to be made, centralization of regulation within one Federal agency (NRC) would be the best approach for all uses of radiation. Congress would be required to expand the role of NRC and a change in the agency would be necessary. Expand current Agreement State program.
	Florida (Health Office)	Support idea that regulatory authority of all agreement materials be turned over to the states with consolidation of federal radiation oversight, guidance, and regulatory functions into one agency, not necessarily DHHS.
	Illinois	Prefer CRCPD proposed new organizational concept that recommends some consolidation of all radiation regulatory functions at federal level. Revise QM and pharmacy rules. Prepare white paper to use as a policy basis to clearly delineate the respective authority and responsibilities of various Federal and State agencies.
	Maryland	Rather than revoke NRC's authority and repeal the Federal regulations, such authority should be expanded to incorporate NARM, and the Federal regulations should be thoroughly reviewed and amended to clarify regulatory responsibility. DHHS does not have necessary expertise.
	Massachusetts	Do not support elimination of all aspects of NRC's medical program, but support relaxation of overly prescriptive and unnecessarily costly requirements. Support intent of single Federal agency providing a single leadership role but do not support automatic selection of DHHS.
	Texas	The basis for the report's recommendations do not seem to be substantiated. The merging of all federal radiation control oversight into a single regulatory program should be considered. The NRC should enhance the partnership with the States to jointly determine compatibility requirements.